



HIGHLIGHTS: Overview of Requirements

- Expanded requirement for reporting medication irregularities to include the medical director.
- Expanded requirement for how pharmacist must document irregularities and how attending physician must respond.
- Added requirement for center policy and procedure on monthly drug regimen review.
- New definition of psychotropic drug as any drug that affects brain activities associated with mental processes and behavior including, but not limited to: antipsychotic, antidepressant, antianxiety and hypnotic.
- Added limitations to PRN psychotropic drug use only when necessary to treat a diagnosed specific condition documented in clinical record.
- Added 14-day limitation on PRN orders for psychotropic drugs with option for extension if attending physician or prescribing practitioner documents rationale in medical record and indicates duration of PRN order.
- Added 14-day limitation on PRN orders for antipsychotic drugs with option for renewal if attending physician or prescribing practitioner evaluates resident for appropriateness of that medication.
- Pharmacist must review resident's medical chart during drug regimen review.
- No change in requirement to ensure center is free from medication error rates of 5% or greater and residents are free from any significant medication errors.



REVIEW & ACTION: Implementation Strategies and Tips

Phase I – by November 28, 2016

- ✓ Licensed pharmacist and center leadership and staff collaborate to develop and maintain monthly drug regimen review policies and procedures including, but not limited to the following:
 - Timeframes for steps in the process
 - Steps pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident
- ✓ In coordination with licensed pharmacist, evaluate status of center's:
 - System of medication records that enables periodic accurate reconciliation and accounting for all controlled medications.
 - Prompt identification of loss or potential diversion of controlled medications; and
 - Determination of the extent of loss or potential diversion of controlled medications.
- ✓ Update practices to be consistent with the following:
 - Involvement of resident, family, representative in medication management process including addressing relative benefit and risks to, and preferences and goals of, the individual resident.
 - Recognition of which medications are considered a psychotropic drug per regulatory description.

- Recognition of what is considered an irregularity (e.g. including, but not limited to, unnecessary drug criteria):
 - Excessive dose (including duplicate drug therapy)
 - Excessive duration
 - Without adequate monitoring
 - Without adequate indications for its use
 - Use in presence of adverse consequences which indicate dose should be reduced or discontinued
- Pharmacist must report irregularities on a separate, written report sent to attending physician, medical director and director of nursing. Reports must be acted upon.
 - Irregularity report will list, at a minimum, resident name, relevant drug and irregularity identified by pharmacist.
 - Attending physician must document in the medical record:
 - Review of identified irregularity
 - What, if any, action has been taken to address irregularity
 - If no change in medication, document rationale in medical record
- ✓ Provide training to staff and physicians/prescribing practitioners on monthly drug regimen review policies, procedures, practices and regulatory requirements.
- ✓ Conduct medication administration observations (including, but not limited to: “shake well” or mix a suspension, crushing medications, administering medications via feeding tube, giving adequate fluids with medications) to identify areas of process improvement and address accordingly.
- ✓ Audit organizational practices related to monthly drug regimen review and medication error rates to ensure they are consistent with policies, procedures and regulatory requirements.
- ✓ Incorporate identified areas for process improvement from steps above into QAPI program. (see § 483.75 Quality assurance and performance improvement).

Phase II – by November 28, 2017

- ✓ Update center and pharmacy practices on monthly drug regimen review to include a review of the resident’s medical chart.
- ✓ Update practices on psychotropic drug use:
 - Residents who have not used psychotropic drugs are not given these drugs unless necessary to treat specific condition as diagnosed and documented in clinical record.
 - Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
 - Limit PRN psychotropic drug orders to 14-days. If extension needed, perform required steps.
 - Limit PRN antipsychotic drug orders to 14-days. If needed after 14 days, perform required steps.
- ✓ Review center’s approach to non-pharmacological interventions and improve effectiveness where possible.
- ✓ Identify residents currently receiving a psychotropic medication, per regulatory definition.

ACTION BRIEF:

§ 483.45 Pharmacy Services

- Determine what has been done in effort to discontinue the medication (e.g. GDR, behavioral interventions).
- If effort to discontinue medication has not been done, is there sufficient documentation of clinical contraindication?
- Update orders for PRN psychotropic or PRN antipsychotic medications to be consistent with regulatory requirements.
- ✓ Provide training to staff and physicians/prescribing practitioners on updated policies, procedures practices and regulatory requirements about monthly drug regimen review and psychotropic drug use.
- ✓ Audit organizational practices related to monthly drug regimen review and psychotropic drug use to ensure they are consistent with policies, procedures and regulatory requirements.
- ✓ Incorporate identified areas for process improvement from steps above into QAPI program. (see § 483.75 Quality assurance and performance improvement).

Phase II Guidance Updates – by October 24, 2022

- F755 Pharmacy Services- Clarified language related to disposal of Fentanyl patches
 - ✓ Provide training to staff on proper disposal of Fentanyl patches
- F757 Unnecessary Medications-Added language related to antibiotic stewardship and F881
 - ✓ Evaluate current Antibiotic Stewardship Program to ensure through use of infection assessment tools, monitoring of antibiotic use, and feedback and education to prescribers that unnecessary antibiotic use is not taking place.
- F758 Unnecessary Psychotropic Medications and PRN Use-Clarified other classes of drugs not listed in the regulation and how they are affected by psychotropic medication requirement; added language on potential misdiagnoses, such as schizophrenia, in order to prescribe antipsychotics.
 - ✓ Identify residents currently receiving other medications (antihistamines, anti-cholinergic medications, and central nervous system agents) with a documented use that appears to be a substitute for an anti-psychotic, anti-depressant, anti-anxiety, or hypnotic.
 - ✓ Review all residents who have a diagnosis of schizophrenia to ensure the medical record includes detailed evaluations by appropriate practitioners and relevant history consistent with professional standards.
 - ✓ Review residents who receive a new active diagnosis of schizophrenia after admission to ensure residents' medical records included detailed evaluations by appropriate practitioners that include documentation of persistent behaviors for the 6 months prior to the start of the antipsychotic medication in accordance with professional standards to ensure proper coding on the MDS. (Cross referenced with I6000 coding Schizophrenia on MDS). See [MDS 3.0 RAI User's Manual \(v1.17.1R\) Errata \(v2\) \(cms.gov\)](#) for more info.

TIPS

- *Form a team to champion compliance and improvement efforts on pharmacy services and medication management. Consider including the Administrator, Director of Nursing, Medical Director, Consultant Pharmacist, Staff Nurse, Social Worker.
- *Medical Director, Director of Nursing and Consultant Pharmacist develop plan for communicating with physicians/prescribing practitioners about response requirements to drug regimen reviews.
- *Explore center's current understanding and capacity to offer behavioral interventions as alternative to psychotropic medications.

RESOURCES: Additional Materials to Help You

- View applicable F-tags [here](#)
- [National Partnership to Improve Dementia Care in Nursing Homes](#)
- [Driving Quality by Operationalizing Business Systems: A Call to Action](#)
- [CMS Nursing Homes landing page](#)

