The National CONSUMER VOICE for Quality Long-Term Care formerly NCCNHR
Center for Medicare Advocacy MedicareAdvocacy.org
JUSTICE IN AGING FIGHTING SENIOR POVERTY THROUGH LAW

A Closer Look at the Revised Nursing Facility Regulations

Unnecessary Drugs and Antipsychotic Medications

Executive Summary

Regulations about unnecessary drugs and antipsychotic drugs have been moved from the quality of care section to the pharmacy services section. Some provisions have been moved but not otherwise changed: these include protection from unnecessary medications, requirements for gradual dose reductions, and the use of behavioral interventions in order to discontinue drugs, "unless clinically contraindicated." In addition, the pharmacy services regulation includes a new discussion of a broader category of psychotropic drugs, along with new controls over "as needed" (PRN) psychotropic drugs. The revised regulations also expand requirements for drug regimen reviews.

Introduction

On September 28, 2016, the Centers for Medicare & Medicaid Services (CMS) released revised nursing facility regulations. These regulations govern most aspects of nursing facility operations, and apply nationwide to any nursing facility that accepts Medicare and/or Medicaid reimbursement. Regulations regarding unnecessary drugs and antipsychotic drugs were moved from the quality of care section to the pharmacy services section.[1]

Acknowledgements

Justice in Aging, National Consumer Voice for Quality Long-Term Care, and Center for Medicare Advocacy created this issue brief in collaboration. This brief is the third of a series explaining important provisions of the revised regulations.

Unnecessary Drugs

As before, the federal regulation protects residents from the administration of "unnecessary drugs," which continue to be defined as drugs that fall into any of the following categories:

- Excessive dose,
- Excessive duration,
- Without adequate monitoring,
- Without adequate indications for use, or
- In the presence of adverse consequences which indicate the dose should be reduced or discontinued.

Psychotropic Drugs

Protections that previously applied solely to antipsychotic drugs have been expanded to all psychotropic drugs. Antipsychotic medications are used primarily to treat psychosis. The category of "psychotropic" drugs includes antipsychotics as well as anti-depressants, anti-anxiety drugs, and hypnotics.

1 The quality of care, and pharmacy regulations are located at sections 483.25 and 483.45, respectively, of Title 42 of the Code of Federal Regulations.

Under the revised regulations, psychotropic drugs may not be given to a resident unless they are "necessary to treat a specific condition as diagnosed and documented in the clinical record." Psychotropic drugs are subject to gradual dose reductions and behavioral intervention "in an effort to discontinue these drugs."

"As Needed" (PRN) Drug Orders

PRN is short for the Latin phrase "pro re nata," which means "as needed." PRN orders for psychotropic drugs are limited to 14 days, although the prescribing physician may document the rationale for a longer duration in the medical record. PRN orders for antipsychotic drugs are more restricted: they are limited to 14 days and the physician's order cannot be renewed unless the physician or prescriber evaluates the resident.

Drug Regimen Review

Each month, a licensed pharmacist must review each resident's entire drug regimen and report irregularities to the attending physician and director of nursing. New regulatory language requires the physician to report the irregularities also to the facility's medical director. Another new provision requires the physician to document his/her review of the pharmacist's report, any action taken to address irregularities identified by the pharmacist, and any rationale for not making recommended changes. Also, facilities are now obligated to develop and maintain policies and procedures for drug regimen review.

Beginning in November 2017, the pharmacist's monthly review of each resident's entire drug regimen must include review of the resident's medical record.

Effective Dates

Most of the provisions related to unnecessary drugs, antipsychotic drugs, and drug regimen review became effective November 28, 2016. The exceptions are provisions relating to medical chart review (part of drug regimen review) and psychotropic drugs, which become effective on November 28, 2017.

Finding the Regulations

Pharmacy services are discussed in section 483.45 of Title 42 of the Code of Federal Regulations.

Tips for Residents and Advocates

Pay attention to the drug regimen and any changes. A positive change in the revised regulations is the expanded reach of the protections against inappropriate use of drugs. As discussed above, this requirement now applies to all psychotropic drugs, rather than the narrower category of antipsychotic drugs. This change may help ensure that nursing facilities do not use medication inappropriately to sedate residents. Close review of all drugs taken by a resident is critical. Ask questions — you should know why each drug was ordered, its potential and actual side effects, possible drug interactions, how the resident has responded to it, and whether efforts have been made to reduce or eliminate its use.

Careful scrutiny of antipsychotics is particularly important. The regulations are disappointing in their failure to take a stronger stand against the use of antipsychotics, particularly when those antipsychotics are used "off-label" to treat a condition other than psychosis. Most commonly, antipsychotic drugs are administered off-label to residents with dementia. The Food and Drug Administration (FDA) has issued its highest warning (Black Box) against the use of antipsychotic drugs for individuals with dementia, warning that such use carries the risk of death and other serious harm. Such off-label use is discouraged by CMS's own National Partnership to Improve Dementia Care in Nursing Homes, which has sought to reduce the inappropriate use of antipsychotic drugs in nursing facilities.

Recognize that no drugs can be administered without consent. Under the resident rights and care planning regulations, residents and their representatives can direct care planning and, as desired, refuse medical treatment.[2] In addition, under state law, a patient must be offered information about a drug's pros and cons, and a drug can be administered only with the patient's consent. Residents and their representatives should never forget that no drug can be administered without the informed consent of the resident or (if the resident does not have capacity to consent) the resident's representative. Thus, residents and their representatives must have information about why a drug is being recommended, and at any time can refuse or withdraw previous consent to any drug.

Ask for assessment and care planning. Too frequently, nursing facilities use psychotropics (including antipsychotics) to address a resident's agitation or other behavior when a better response would be to seek strategies that do not rely on drugs. The best dementia care is based on determining the resident's needs, and seeing a resident's behavior as a method of non-verbal communication, rather than as something to be suppressed with drugs. Residents and their representatives should not be shy in asking the nursing facility to assess possible medical, environmental, and psychosocial causes of agitation and to adjust its care practices in order to better meet a resident's needs. A good place to start is the care planning process, which is discussed in the first issue brief in this series.

2 *See* 42 C.F.R. §§ 483.10(c) (right to participate in care planning, including right to request, refuse, or discontinue treatment), 483.21 (care planning).