**Drug Regimen Review**

**Requirements of Participation Checklist**

**Tool:  DRUG REGIMEN REVIEW POLICY CHECKLIST**

**F756**

**483.45(c): “The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.”1**

**Purpose and Intent of 483.45(c):**

The purpose of this Drug Regimen Review Policy Checklist is to provide an outline to guide the facility in the development of a comprehensive Drug Regimen Review Process that provide both the quality of care for the facility resident population and compliance with regulations.

The intent of this requirement is that the facility maintains the resident’s highest practicable level of physical, mental, and psychosocial well-beingand prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing (DON)*.*

To assure that the individual facility has followed all the required steps for the development and implementation of a comprehensive Drug Regimen Review Policy in accordance with the Requirements of Participation, the following checklist captures specific action items for successful completion.  The far-left column represents the actual RoP language, and the right column indicates specific leadership strategies for successful completion and implementation of the RoP. When preparing updated policies and procedures, it is recommended to include actual RoP language as applicable.

**Suggested Checklist:**

**Comprehensive Drug Regimen Review Policy and Procedure**

| **Regulation** | **Recommended Actions** |
| --- | --- |
| **F756****“483.45(c) Drug Regimen Review.**(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.”1(2) “This review must include a review of the resident’s medical chart.”1(4) “The pharmacist must report any irregularities to the attending physician and the facility’s medical director and director of nursing, and these reports must be acted upon. (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug. (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility’s medical director and director of nursing and lists, at a minimum, the resident’s name, the relevant drug, and the irregularity the pharmacist identified. (iii) The attending physician must document in the resident’s medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident’s medical record.”1(5) “The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident. |  Review, revise, and institute a Drug Regimen Review Policy and Procedure in accordance with F756. Update all definitions and terms:* Adverse consequence,
* Clinically significant,
* Dose,
* Excessive dose,
* Duration,
* Excessive duration,
* Irregularity,
* Medication interaction,
* Medication regimen review (MRR)

 Review pharmacy consultant agreement to align with requirements and expectations. Review pharmacy consultant agreement with Medical Director.  Review pharmacy consultant agreement to include medical chart review. Pharmacist and MD documentation guidelines updated with new regulatory language. Update a system for the pharmacist to track responses to recommendations and has a process in place to address issues that do not receive a timely response. Update a system for the DON to track responses to recommendations and has a process in place to address issues that do not receive a timely response. Ensure pharmacy recommendations are part of the resident’s medical record or are kept in the facility for reference. Review system for notification and review with Medical Director related to requirements, Practitioner’s responses and documentation of pharmacy recommendations. Provide staff education on the revised Drug Regimen Review Policy.  Update training for orientation, annual, agency staff, as needed. Evidence of education will include sign in sheets. |
| **F757 Unnecessary Drugs**“Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used— 1) In excessive dose (including duplicate drug therapy); or 2) For excessive duration; or (3) Without adequate monitoring; or (4) Without adequate indications for its use; or §483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or (6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.” |  Review and update the Policy and Procedure for Unnecessary Drugs in collaboration with the Drug Regimen Review Policy. |
| **F758**“§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic (ii) Anti-depressant; (iii) Anti-anxiety: and (iv) Hypnotic”**Psychotropic Drugs.** Based on a comprehensive assessment of a resident, the facility must ensure that—(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record; 2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs; 3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and 4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in (5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident’s medical record and indicate the duration for the PRN order. 5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.”1 |  Review and update the Policy and Procedure for the use of Psychotropic Medications/Chemical Restraints outlining use, alternatives and reduction plans. Review and update the Policy on Gradual Dose Reductions for Psychotropic Medications/Chemical Restraint. |
| **F710 Physician Services**“A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident’s immediate care and needs.**Physician Supervision**The facility must ensure that— §483.30(a)(1) The medical care of each resident is supervised by a physician; §483.30(a)(2) Another physician supervises the medical care of residents when their attending physician is unavailable.”1“Supervising the medical care of residents means participating in the resident’s assessment and care planning, monitoring changes in resident’s medical status, and providing consultation or treatment when contacted by the facility”1 |  Review policies and procedures related to physician notification of MRR recommendations including, for example, irregularities or need for gradual dose reduction, etc. Review with attending physician documentation of responses regarding recommendations |

The below areas serve as a cross reference for facility leaders to conduct addition policy and procedure review across departments to incorporate the changes set forth in **483.45(c)** Drug Regimen Review processes and procedures. This listing is not all encompassing however should serve as a resource for leaders as they update their internal policies, procedures and operational processes.

CMS Definitions

Employee Orientation

Annual Training Requirements

Quality Assurance and Performance Improvement

Staff Training and Education

Unnecessary Drugs Policies and Procedures

Incident Accident Policy and Procedure

Behavior Management

Physical Device and Chemical Restraint Policy and Procedure

Primary Care Physician Roles and Responsibilities

Medical Director Requirements

Medical Record Retention Protocols

**Reference**

1Centers for Medicare & Medicaid Services State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities (Rev. 173, 11-22-17) Advance Copy, 2022: <https://www.cms.gov/files/document/appendix-pp-guidance-surveyor-long-term-care-facilities.pdf>