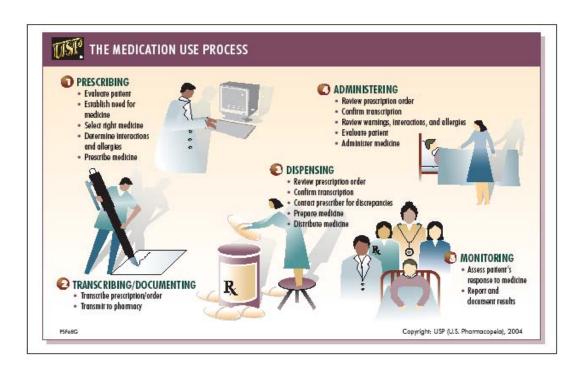


THE MEDICATION USE PROCESS

The Long Term Care Professional Leadership Council (LTCPLC) supports the medication use process in long term care as an essential tool for providing safe, effective, and optimal pharmaceutical care. The LTCPLC also supports a collaborative approach to analyzing systems and improving the quality of the medication use process in the skilled nursing facility.

What is the Medication Use Process?

The medication use process involves several steps: 1) prescribing, 2) transcribing and documenting, 3) dispensing, 4) administering, and 5) monitoring. The United States Pharmacopeia illustrates the process below:



NOTE: This diagram is used to illustrate the sequential steps in a process and is not intended to illustrate or represent specific roles of providers or caregivers involved in the process, as some roles are often performed by a variety of providers.

The following diagram shows how the five steps of the Medication Use Process (Prescribing, Transcribing/Documenting, Dispensing, Administering, and Monitoring; Figure 1 above) are linked to the Care Delivery Process. The first two phases of the Care Delivery Process (Recognition/Assessment and Diagnosis/Cause Identification) are the foundation for the Medication Use Process, which is a key component of Phases 3 (Selecting Interventions / Delivering Care) and 4 (Monitoring) of the Care Delivery Process.

Care Delivery Process	Medication Use Process
1. Recognition / Assessment	
2. Diagnosis / Cause Identification	
3. Selecting Interventions / Delivering Care <====>	1. Prescribing
	2. Transcribing / Documenting
	3. Dispensing
	4. Administering
4. Monitoring <=====>	5. Monitoring

If a dose adjustment is made or another drug is prescribed, the medication use process begins again. The medication use process involves some very complex components, each of which requires proper oversight and coordination to assure that residents receive each of their medications in a safe manner that maximizes effectiveness and reduces risks.

Regulations and the Medication Use Process

Effective 12/18/06, CMS published significant revisions to the State Operations Manual Guidance to Surveyors for Unnecessary Drugs (F329) and Pharmacy Services (F425, F428, and F431). These changes implied increased responsibility of the nursing staff, medical director, consultant pharmacist, and pharmacy providers to assure appropriate medication management and pharmacy services in skilled nursing facilities. The details of F-329, Unnecessary Drugs, address the prescribing and monitoring aspects of the medication use process, while F425, 428, and 431 address the dispensing portion. Finally, F332 and F333, Medication Errors address the process of administration of medications.

The intent of these requirements is that each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

- 1) The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- 2) Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- 3) Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- 4) Clinically significant adverse consequences are minimized; and
- 5) The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

SOURCE: UNNECESSARY MEDICATIONS: INTERPRETIVE GUIDELINES AND SEVERITY GUIDANCE 2006 CENTERS FOR MEDICARE AND MEDICAID SERVICES

Implications

F329 retains previous requirements that medications should be supported by a current diagnosis or indication for use, that appropriate doses are used, that drugs are given for appropriate duration and are monitored properly (via resident assessment, laboratory tests, vital signs, etc.), and that no adverse drug reactions are present that would indicate the need to change or discontinue a medication.

New F329 requirements have additional implications for nursing facilities and for the process of medication administration. For example, dosing of medications will be more closely evaluated with respect to manufacturer recommendations. This could mean that some medications ordered three times a day may have to be given at times other than the facility's standard times for three times daily, such as before, with, or after a meal. Nursing staff will need to be able to identify these medications and assure their timely administration. Facilities may ask their pharmacy providers to identify these drugs when dispensed and to label them for administration at appropriate times. Medication effectiveness may be impacted by timing of medication administration with respect to meals.

Other implications for the facility include the identification of specific adverse drug effects known as "black box warnings." Nursing staff will need to rely on prescribers and pharmacists to help identify these drugs when ordered and will need to develop appropriate plans for monitoring for those specific adverse reactions. Similarly, an interdisciplinary approach will be needed in order to properly identify and monitor medications with significant anticholinergic properties, to dose antipsychotic medications within daily thresholds, and to evaluate the risks and benefits of higher-risk medications.

Expectations for considering gradual dose reductions now apply to more classes of medications. Facilities need guidelines for attempting dose reductions and monitoring the results. Behavior monitoring becomes an even more critical component of the process of attempting gradual dose reductions for psychopharmacological medications.

F425 requirements for medication regimen reviews for short stay residents and for residents with a significant change of condition will require greater coordination of information between the consultant pharmacist and the facility about residents who need these interim reviews.

Oversight of all pharmacy services, including multiple pharmacy providers, falls upon the consultant pharmacist as part of a collaborative process within the facility.

What should be done to ensure that the medication use process is fully implemented? The new F329 surveyor guidance increases the importance of a collaborative interdisciplinary approach to assessing, evaluating, and improving all processes related to a facility's medication management system. In order for the medication use process to occur properly and benefit the residents, the facility needs to ensure that it has an intact, properly functioning medication management system.

The F329 guidance emphasizes the link between the medication use process and the care delivery process. The LTCPLC believes that compliance with F329 requires that each facility commit to consistent, correct, and complete adherence to the care delivery process (see LTCPLC statement #2, at member websites). Compliance with F329 is not a separate and distinct obligation, nor is it just about paper compliance.

A growing body of literature warns against overmedication of the elderly and promotes appropriate assessment and cautious prescribing in this vulnerable population. This implies the need for detailed knowledge of drug therapy of the elderly by prescribers and pharmacists. Enhanced collaboration at both the initiation of medication therapy and assessment of effectiveness and continued need (i.e. the prescribing and monitoring steps of the medication use process) will assure the safest and most effective medication selection and use.

The technical aspects of the medication use process - accurate transcription of orders, dispensing and administration of the prescribed medication - involve complex communication processes between the nursing facility and pharmacy. Errors in medication administration can be particularly serious in the frail elderly, and according to the literature, occur at unacceptable rates. Current error prevention experts advise a shift in the culture of error detection and prevention from punitive to non-punitive to enhance reporting of errors. In addition, a root-cause, systems analysis approach is desired instead of the incidental correction commonly seen today.

At a minimum, the administrator, director of nursing services, pharmacist, and medical director should oversee a collaborative quality improvement initiative to oversee a facility's medication management system including proper implementation of the medication use process. This team oversight is also needed for appropriate quality assurance, including root cause analysis and process improvement.

The team needs to assess its systems and processes and evaluate the results of those assessments regularly, identify root causes of any system issues, and then implement process improvements. This involves cooperation among physicians, the pharmacy provider, facility management, and the nursing staff.

Summary and Recommendations

Safe and effective use of medications in the skilled nursing facility involves the coordinated efforts of many individuals, including prescribers, pharmacists, nursing staff, and facility administration. The medication use process ties in closely with the entire care delivery process and provides a good framework for assessing the quality of a facility's systems and processes. Optimizing the medication use process is a key part of improving the entire care delivery process, and vice-versa. Routine assessment and fine tuning of a facility's medication management system can help assure that its medication use process results in the best possible outcomes of drug therapy for its residents and patients. That, in turn, is the preferred route to compliance with F329.

1 May be viewed as part of the CMS State Operations Manual at http://www.cms.hhs.gov/transmittals/downloads/R22SOMA.pdf (viewed on 6/14/08).