Changes in the State Operations Manual: Implications for Consultant Pharmacy Practice

Long-term care facilities are subject to annual reviews by surveyors, who must follow regulations issued by the Centers for Medicare & Medicaid Services. Recent revisions to the State Operations Manual, which provides guidance to the surveyors about how to conduct the review, signal important changes in the way consultant pharmacists will be held accountable for medication use in these facilities.

Key words: Centers for Medicare & Medicaid Services, Consultant pharmacist, F-tags, interpretive guidelines, Long-term care, Nursing facilities, State Operations Manual.

Abbreviations: CMS = Centers for Medicare & Medicaid Services, GDR = Gradual dose reduction, MRR = Medication regimen review, SOM = State Operations Manual.

First of a series

Next: What the new State Operations Manual regulations will mean to your practice.

On September 15, 2006, the Centers for Medicare & Medicaid Services (CMS) released the revised version of the "bible" of consultant pharmacists: the survey guidance for Pharmacy Services and Unnecessary Medications in Appendix P and Appendix PP of the State Operations Manual (SOM). The manual outlines, in detail, what state reviewers must consider when reviewing pharmacy services provided in long-term care facilities—an annual review required by federal regulation.[1] While these changes may be new to many consultant pharmacists, these revisions actually reflect work that has been in process for many years. The SOM revisions are the work of CMS and expert panels, which incorporated public comments from numerous organizations, including ASCP. The culmination: guidelines that will be implemented in the nursing-home survey procedure beginning December 18, 2006.

This revision —the first substantive change in these sections since 1999 –signals important changes in the way consultant pharmacists will be held accountable for medication use in long-term care facilities.

The regulations and new guidance to surveyors apply to portions of Appendix P and F-Tags 329, 425, 428, and 431 of Appendix PP of the SOM. However, they only apply to skilled nursing facilities and nursing facilities that meet the requirements for each set forth in the Social Security Act. The new guidelines do not affect intermediate care facilities, assisted living facilities, or hospitals (except portions of a hospital that are licensed as skilled nursing facilities or nursing facilities).

What Really Has Changed?

It is important to keep in mind that the regulations themselves have not changed. Rather, it is the "Guidance to Surveyors," including the interpretive guidelines, investigative protocol, deficiency categorization or severity guidance that have been updated in Appendix P and Appendix PP of the SOM. The revisions to Appendix PP include four pharmacy

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"tags" (the alphanumeric labeling scheme of the SOM), reflecting a consolidation of 11 previous tags (Table 1). The new Tag F329 focuses on unnecessary medications, while Tags F425, 428, and 431 focus on overall pharmaceutical services. A thorough understanding of the changes to the guidelines is critical for consultant pharmacists as they work with facilities to provide the highest level of care for patients and comply with the standards set by CMS.

More Holistic View

According to CMS, the revisions to the tags reflect a broadening of the focus toward assessing all aspects of medication management, rather than only specific categories of medications (i.e., psychoactive). The revisions offer additional guidance on monitoring for medication effectiveness and assessing medications that may cause or exacerbate symptoms that they were intended to treat or prevent. In general, the revisions encourage a more holistic view of the medication regimen, where the risks and benefits of any one medication must be viewed in relation to the entire drug regimen. Specifics follow.

This is the first substantive change in these sections since 1999 and signals important changes in the way consultant pharmacists will be held accountable for medication use in long-term care facilities.

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Table 1. Tags Combined Under the Revised State Operations Manual

Unnecessary Medications

New Tag F329 = Old Tags F329, F330, F331

Pharmaceutical Services

New Tag F425 = Old Tags F425, F426, and F427 (b)(1)
Focuses on Pharmaceutical Services and Procedures

New Tag F428 = Old Tags F428, F429, F430
Focuses on Medication Regimen Review

New Tag F431 = Old Tags F427(b) (2) and (3); F431, F432
Focuses on Labeling and Storage of Medications, including Controlled Medications

Figure 1. F329 Regulations

Each resident's drug regimen must be free from unnecessary medications. An unnecessary drug is any drug when used:

- In excessive dose (including duplicate therapy), or
- For excessive duration, or
- Without adequate monitoring, or
- Without adequate indications for its use, or
- In the presence of adverse consequences that indicate the dose should be reduced or discontinued, or
- Any combinations of the reasons above

Tag F329: Unnecessary Medications

While all of the tags are equally important, it is likely that much of the impact will be felt in the changes to Tag F329, "Unnecessary Medications." This tag now emphasizes that *any* drug is potentially inappropriate or unnecessary, based on dose, duration, indication for use, etc. (Figure 1). And although the guidelines generally emphasize the older adult resident > 65 years old, adverse consequences can occur at any age, so CMS considers these requirements applicable to all.

Indication

The presence of a diagnosis may not, in itself, be sufficient to warrant the use of a medication. Rather than simply match matching diagnoses with medications, consultant pharmacists (and prescribers) will need to take advantage of the many opportunities or circumstances that call for evaluation of a medication's indication. These include admission/readmission, any time multiple prescribers are involved or new medications are ordered, or when a health professional observes changes in the patient's condition—such as distressed behavior.

Such an evaluation of an indication involves looking at whether:

- An appropriately detailed evaluation/assessment has occurred in these situations
- Other causes of symptoms have been ruled out
- The signs and symptoms are persistent or clinically significant enough to warrant medication use

Additionally, surveyors will be looking to see that the facility has attempted nonpharmacological interventions (e.g., redirection of behaviors) whenever possible.

Gradual Dose Reduction/Tapering*

(See box, page 961)

While the traditional focus of gradual dose reduction (GDR) or tapering has been on psychoactive

medications, the guidance document emphasizes the importance of seeking:

- An appropriate dose and duration for all medications if the resident's clinical condition has improved/stabilized
- Whether the underlying causes of the symptom have resolved
- Whether nonpharmacological interventions have been tried and were effective

Nonetheless, specific classes of medications are mentioned in the document, including antipsychotics, sedatives/hypnotics, and psychopharmacological medications.

Antipsychotics and sedatives/hypnotics were included in the previous guidelines, but "psychopharmacological" is a new class. It is defined as "Any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders." Based on this definition, many different types of medications could be considered "psychopharmacological," including anticonvulsants, antidepressants, and anxiolytics.

Especially important, included within these classes of medications are both the "older" and "newer" (and both "short-acting and "long-acting") agents, as well as medications used off-label for the purpose identified (e.g., trazodone for sleep). The revised guidelines therefore create an important distinction, in which medications are generally being defined by how they are being used rather than the pharmacologic class to which they belong.

Antipsychotics

No matter whether antipsychotics are used to treat behavioral symptoms or psychiatric disorders, within the first year in which a resident is admitted on an antipsychotic, or within the first year after the facility initiates an antipsychotic, GDR must occur in two separate quarters with at least one month between attempts, unless clinically contraindicated. After the first year, unless clinically contraindicated, GDR must occur annually.

Clinically contraindicated means symptoms returned or worsened after the most recent attempt at a GDR *within the facility*. In addition, the prescriber must have documented a clinical rationale why, at this time, additional GDR would be likely to impair the resident's function, increase distressed behaviors, or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Sedatives/Hypnotics

If used routinely (see additional clarification below), unless clinically contraindicated, tapering should be performed quarterly. Clinically contraindicated means tapering must have been attempted during the previous three quarters *and* the physician has documented clinical rationale why, at this time, additional

Psychopharmacological is defined as "Any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders."

What About the "Beers List?"

While the "Beers List" may not necessarily be listed in its entirety, medications included in this list (of medications inappropriate for the elderly) have been incorporated into parts of the revised State Operations Manual (SOM). The revised SOM contains several reference tables, including, for example, a table of "Medication Issues of Particular Relevance," which alphabetically lists examples of some categories of and/or specific medications that have limited indications for use, require precautions when used, have specific monitoring needs, or have the potential to cause clinically significant, adverse consequences.

Medications listed in this 36-page table should not be considered absolutely contraindicated, but do warrant evaluation of the risks and benefits on an individual basis. Another table in the revised SOM lists numerous categories of "Anticholinergic Medications," which suggests that the use of these medications will continue to fall under intense scrutiny by surveyors.

tapering would be likely to impair the resident's function, increase distressed behaviors, or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

The only class of medication that specifically identifies a time limit, or "expiration," for clinical contraindication is the sedatives/hypnotics. Once clinical contraindication has been decided, it is valid for one year. For the sedatives/hypnotics, tapering attempts apply when the medication is used "routinely." Since "routinely" is a general term and could be subject to interpretation, CMS has verbally provided ASCP with additional guidance, which it will use during surveyor training. This clarification is that "routinely" generally means that a sedative/hypnotic is used approximately 50% of the time or more. This information is especially helpful for sleep medications used on an "as-needed" basis.

Other Psychopharmacological Medications

The GDR time frames and terms for clinical contraindication for psychopharmacological medications are the same as those for antipsychotics (see above).

Medication Monitoring

The guidelines contain specific language on monitoring medications.

Monitoring for adverse consequences involves ongoing vigilance and may periodically involve objective evaluation (e.g., assessing vital signs may be indicated if a medication is known to affect blood pressure, pulse rate and rhythm, or temperature). Using quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility.

Included in the document is a list of potential monitoring tools. While this list is not intended to be all-inclusive, it does provide a starting point from which consultant pharmacists can help facilities develop medication-monitoring policies and procedures (see Table 2).

Duplication of Therapy

The guidelines clearly state that duplication of therapy, i.e., use of two or more medications from the same class **or** use of medications from different therapeutic categories that have similar effects/properties, is generally not indicated. The use of multiple products containing acetaminophen, or multiple laxatives, benzodiazepines, or medications with anticholinergic side effects, for example, will require documentation to clarify the rationale and benefits for use as well as parameters for monitoring.

Tag F425: Pharmaceutical Services and Procedures

The revisions to Tag F425 are a significant change to the survey process ---this is the first time that surveyors have been provided with specific instructions on assessing

Table 2. Examples of Monitoring Tools from F329

Common Conditions/Symptoms	Examples of Tools	Potential Applications	Source/Reference
Diabetes	Blood glucose, Hemoglobin A1C	Diagnose diabetes and determine diabetic control	www.endocrineweb.com/diabetes/diagnosis.htm www.diabetes.org/home.jsp www.diabetes.niddk.nih.gov/ www.diabetesbox.com/HbA1c.asp
Alzheimer's Disease/Dementia	Mini-Mental Status Exam (MMSE)	Determine degree of cognitive impairment	www.emedicine.com/med/topic3358.htm www.fpnotebook.com/NEU75.htm
Functional Decline	Instrumental Activities of Daily Living (IADL)	Assess functional capabilities	www.cdc.gov/nchs/datawh/nchsdefs/iadl.htm www.fpnotebook.com/GER3.htm
	Resident Assessment Instrument (RAI)	Assess aspects of nursing home resident's behavior and function	www.cpadiv20.phhp.ufl.edu/rai.htm www.careplans.com/pages/library/RAI_user_guide.pdf
	Functional Alzheimer's Screening Test (FAST)	Assess level of function in individuals with dementia	http://geriatrics.uthscsa.edu/educational/med_students/fastscale_comm.htm
Delirium	Confusion Assessment Method (CAM)	Screen for cognitive impairment and delirium	www.hartfordign.org/publications/trythis/issue13.pdf http://elderlife.med.yale.edu/pdf/The%20Confusion%20Assessment%20Method.pdf
Bipolar Disorder	Mania Rating Scale	Assess severity of mania	www.psychiatrypractice.com/AssessmentTools/default.aspx?11=3&12=3&13=&13= www.brainexplorer.org/factsheets/Psychiatry%20Rating%20Scales.pdf
Pain	List of pain scales	Assess pain characteristics (e.g., intensity, impact, timing)	www.chce.brown.edu/pcoc/Physical.htm
Depression	Geriatric Depression Scale	Screen or monitor individuals at risk for depression	www.assessmentpsychology.com/geriatricscales.htm www.hartfordign.org/publications/trythis/issue04.pdf www.merck.com/mrkshared/mmg/tables/33t4.jsp
	Cornell Depression in Dementia Scale	Screen or monitor for depression in individuals with cognitive impairment	www.emoryhealthcare.org/departments/fuqua/CornellScale.pdf
Abnormal Movements	Abnormal Involuntary Movement Scales (AIMS)	Assess presence and severity of involuntary movements that may be due to disease or medications	www.carepaths.com/pages/Instruments_AIMS.asp www.mhsip.org/library/pdfFiles/abnormalinvoluntarymovementscale.pdf
Behavioral Symptoms Associated with Dementia	Neuropsychiatric Inventory Nursing Home Version (NPI-NH)	Screen or monitor for behavior associated with dementia (e.g., hallucinations, agitation, or anxiety)	www.alzheimerinsights.com/insights/vol2no3/vol2no3.htm
	Behavioral Pathology in Alzheimer's Disease Rating Scale (Behave-AD)	Provide a global rating of noncognitive symptoms	www.alzforum.org/drs/dic/res/neuropsychological.asp
	Cohen-Mansfield Agitation Inventory (CMAI)	Assess/rate distressed behavior in older individuals	www.researchinstituteonaging.org/assessment.html www.geriatrictimes.com/g010533.html

Table 3. F425 Consultant Pharmacist Responsibilities

The State Operations Manual clearly spells out in detail the responsibilities of the long-term care pharmacy. In addition, it contains an extensive list of the consultant pharmacist's responsibilities to be accomplished in collaboration with the facility. These include:

- Developing, implementing, evaluating, and revising (as needed) policies and procedures related to pharmaceutical services, including intravenous (IV) therapy
- Coordinating pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans)
- Developing IV therapy procedures if used within the facility (consistent with state requirements). This may include determining competency of staff and facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures
- Determining (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitoring the use, replacement, and disposition of the supply
- Developing mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services
- Striving to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants
- Providing feedback about performance and practices related to medication administration and medication errors
- Participating on the interdisciplinary team to address and resolve medication-related needs or problems

Establishing Procedures

Other pharmacist responsibilities include establishing procedures for:

- Conducting the monthly medication regimen review (MRR) for each resident in the facility
  - Addressing the expected time frames for conducting the review and reporting the findings
  - Addressing the irregularities
  - Documenting and reporting the results of the review (See F428 for provision of the review)
  - Addressing MRRs for residents who are anticipated to stay less than 30 days or experience an acute change of condition, as identified by facility staff
- Contacting a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber
- Developing the process for receiving, transcribing, and recapitulating medication orders
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors
- Ensuring that if automated medication delivery devices or cabinets are used, they include:
  - The types or categories of medications
  - Amounts stored
  - Location of supply
  - Personnel authorized to access the supply
- Establishing policies for record keeping, monitoring for expiration dates, methods to ensure accurate removal of medications, steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system
- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services. This includes policies for delivery and storage systems within the various locations of the facility to prevent, to the degree possible, loss or tampering with the medication supplies and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors
- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information
- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families

the provision of pharmaceuticals and related services to the facility. It is also the first mention of specific examples of responsibilities and activities that the consultant pharmacist and facility may collaborate on to ensure the provision of these services (Table 3).

According to the F425 regulations, the facility must:

- Provide routine and emergency medications and biologicals to its residents or obtain them under an agreement
- Provide pharmaceutical services, including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all medications and biologicals, to meet the needs of each resident
- The facility must employ or obtain the services of a licensed pharmacist who provides consultation on all aspects of the provision of pharmacy services in the facility

Acquiring Medications

The previous F425 guidelines said merely that medications must be provided in a timely manner; the revised F425 encompasses the full spectrum of pharmaceutical services, ranging from ordering to administration of medications. It also emphasizes that acquisition of medications encompasses all aspects of the medication delivery process, including obtaining medication from an emergency supply kit.

Facilities and pharmacies will need to ensure that adequate policies and procedures exist regarding who contacts the pharmacy to acquire medications and who verifies and clarifies orders. Surveyors will continue to assess the timeliness of medication acquisition based on general criteria found in the guidelines. However, surveyors and providers are expected to use their clinical judgment, on a case-by-case basis, to determine how quickly medication is/was acquired.

Appropriate transport of medications from the pharmacy to the facility may also be reviewed, with surveyors, for example, looking at who transports the medications, the adequacy of security measures, and whether medications are maintained in proper fashion (i.e., refrigerated medications kept on ice) during transport. The receipt of medications in the facility may also be scrutinized, with surveyors evaluating which staff members are authorized to receive medications, where medications are kept until stored in the medication cart, and who reconciles the orders and notifies the pharmacy of discrepancies.

Administering Medications

The administration of medications always has been a focus of the survey process. Ensuring the "Five Rights"

Any symptom or change in a resident could be medication-related and should be evaluated.

(right patient, right drug, right dose, right time/frequency and right route) of medication administration continues to be a high priority for surveyors implementing the revised SOM guidelines. Although the new F425 tag addresses procedural aspects of medication administration, Tags F332 and F333, dealing with medication errors, are still in effect. In fact, aspects of the new F425 guidelines now have been incorporated into the surveyor's medication-pass observation, which is detailed in Task 5E of Appendix P.

Facilities will be held accountable for providing an environment that allows for continuity and consistency of staff administering medications, minimizing unnecessary interruptions, and having appropriate and well-defined schedules of administration and monitoring. Additionally, there will be an increased focus on medications given via routes other than oral — particularly those given intravenously —requiring facilities to have and to follow specific policies and procedures for administering medications using alternative (non-oral) routes. Appropriate documentation of medication administration and disposal of medications also may be assessed.

Labeling and Storing Medications

While details are provided on appropriate labeling and storage of medications in the guidelines at F431, procedural aspects of labeling and storage are included at F425 as well. The consultant pharmacist and facility jointly should review new policies and procedures for the proper labeling of medications prepared by facility staff (such as IV admixtures) as well as labeling of medications when the frequency or dose has changed. Surveyors may review the environmental conditions of storage areas as well as the location, security, and access to medication-storage areas. They may also look to see that medications with unique storage parameters or labeling requirements, such as multiuse vials, are being appropriately stored and their expiration dates monitored.

F428: The Medication Regimen Review

While other tags include examples of the consultant pharmacist's responsibilities, Tag F428 is most directly related to the traditional role of the consultant pharmacist. In addition to providing a definition of the medication regimen review (MRR) (see box, below), this tag provides detailed instruction regarding the timing, location, and important considerations employed in the MRR process.

According to the new guidelines, the consultant pharmacist and facility are responsible for developing procedures for the MRR (e.g., who, when, where), including expedited reviews for residents who are expected to have a short stay (less than 30 days) or residents who experience an acute change in condition.

Definition of Medication Regimen Review

While consultant pharmacists have performed medication regimen reviews (MRR) for decades, the new State Operations Manual to be implemented on December 18, 2006, provides the first formal definition of the MRR:

> *MRR is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication.*

The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.

The revised guidelines also provide guidance regarding where the MRR is performed.

Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities, or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the facility's staff, reviewing the medical record, and observing and speaking with the resident. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

This provision may become increasingly important as facilities and pharmacists determine methods for performing MRR on short-stay residents (i.e., patients admitted for two weeks of post-op rehab or for a short course of IV antibiotic therapy), with the revised guidelines emphasizing that pharmacists are expected to provide MRR more often than every 30 days, if necessary.

F428 also lists numerous factors to be considered in the MRR process, encouraging consultant pharmacists to assess whether recent changes in a resident's condition may be related to medications. In other words, consultant pharmacists will need to assess whether problems sometimes referred to as "geriatric syndromes" might actually be an adverse medication effect (Table 4). Tag F428 also suggests that consultant pharmacists may identify and report concerns in several medication-related problem categories (Table 5).

Upon completion of the MRR, the pharmacist will document "either that no irregularity was identified or the nature of the irregularities." Exact parameters regarding the timeliness with which the pharmacist notifies the facility and/or prescriber of irregularities is not provided. Instead, it depends on several factors: the potential for, or presence of, serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants, or in cases of possible allergic reactions to antibiotic therapy. The pharmacist's findings, while not

Table 4. F428 Medication Regimen Review Considerations Related to "Geriatric Syndromes"

- Anorexia and/or unplanned weight loss, or weight gain
- Behavioral changes, unusual behavior patterns (including increased distressed behavior)
- Bowel function changes (including constipation, ileus, impaction)
- Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset
- Dehydration, fluid/electrolyte imbalance
- Depression, mood disturbance
- Dysphagia, swallowing difficulty
- Excessive sedation, insomnia, or sleep disturbance
- Falls, dizziness, or evidence of impaired coordination
- Gastrointestinal bleeding
- Headaches, muscle pain, generalized aching or pain
- Rash, pruritus
- Seizure activity
- Spontaneous or unexplained bleeding, bruising
- Unexplained decline in functional status (e.g., activities of daily living, vision)
- Urinary retention or incontinence

Table 5. F428 Medication-Related Problems

According to the new State Operations Manual to be implemented on December 18, 2006, medication-related problems include:

- The use of a medication without identifiable evidence of adequate indications for use
- The use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered
- The use of an appropriate medication that is not helping to attain the intended treatment goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons
- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences
- The presence of an adverse consequence associated with the resident's current medication regimen
- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings
- Presence of medication errors or the risk for such errors
- Presence of a clinical condition that might warrant initiation of medication therapy
- A medication interaction associated with the current medication regimen

required to be part of the active clinical record, must be accessible in the facility. It also should be noted that the new guidelines do not attempt to define the format of the consultant pharmacist's report. Instead, they have attempted to provide flexibility to the facility and pharmacist to determine what type of report (written, electronic, etc.) works for them. Documentation of the MRR and notification of the prescriber and facility may occur electronically, with the facility and pharmacist collaborating on the most effective means to do so.

Pharmacist Recommendations; Physician Actions

Naturally, an ongoing question for consultant pharmacists is, "What do I do about pharmacy consults that have been disregarded or rejected by the physician?"

The regulations at F428 say that the physician and/or director of nursing must act upon the MRR. The new guidelines state that it is not acceptable for a physician to document only that he/she disagrees with the report without providing some basis for disagreeing. If there is potential for serious harm to the resident as a result of a physician's refusal to follow a consultant pharmacist's recommendation, F428 directs that the facility and consultant pharmacist contact the medical director. Or, if the attending physician and the medical director are the same, it says to follow established facility procedure to resolve the situation. F428 provides no specific time frame for when a report that is not acted upon officially becomes delinquent.

The revised tag states:

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist's recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

F431: Storage, Labeling, Controlled Medication

Few substantive changes have been made in Tag F431, although it does include updates regarding labeling of medications prepared by the facility staff, labeling of multidose products, access to medications, and the consultant pharmacist's role in handling

discrepancies found with controlled medications. F431 includes language that alerts surveyors and providers that pharmacy technicians or assistants may be given access to medications for conducting specific tasks such as medication cart exchange and medication cart inspections. It also states that the consultant pharmacist is not required to actually perform reconciliation of controlled substances within a facility. Rather the pharmacist should evaluate and determine that the facility maintains an account of all controlled medications and that the facility completes the reconciliation according to established procedures and state/federal requirements.

Summary

Changes to the SOM will most certainly have an impact both on consultant pharmacists and dispensing pharmacies servicing nursing homes. Consultant pharmacists will play an integral role in educating facility staff and other providers on the most up-to-date information regarding the new survey guidelines. A multidisciplinary approach will be a key component in this preparation process. A primary theme of the revised survey guidelines is this—any symptom or change in a resident could be medication-related and should be evaluated, requiring the involvement of all departments and levels of providers.

Reference

1. McSpadden C. Consultant pharmacists and the survey process. Consult Pharm 2006;21:556-60.

New Changes to State Operations Manual

On November 6-9, 2006, at a training session in Baltimore, Maryland, ASCP learned that the Centers for Medicare & Medicaid Services has introduced some changes to gradual dose reduction (GDR)/tapering in the F329 guidelines, which are effective December 18, 2006:

- Failed GDR/tapering is not the only way clinical contraindication can be determined for:
  - — Antipsychotics used to treat psychiatric conditions
  - — Sedatives/hypnotics
  - — Psychopharmacological medications

  As long as the medication is used in accordance with relevant current standards of practice, tapering/GDR may be considered clinically contraindicated if the physician has documented clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.
- If tapering is used for sedatives/hypnotics, the most recent failed attempt—rather than three previous failed attempts—determines clinical contraindication. Additional direction was added to consider tapering of sedative/hypnotic if it is used beyond the manufacturer's recommendations for duration of use.
- Under the cognitive enhancers section of the guideline's Table 1 in F329, the reference to tapering of psychopharmacological medications has been deleted.

For more information on these changes and other resources on the new nursing home survey guidelines, visit http://www.ascp.com/som.

Conflicts Between the Revised SOM Guidelines and Medicare Part D?

Many pharmacists and prescribers are finding that the only medications in certain classes that are available or easily accessible through Medicare Part D plans are those that are also listed in F329 as potentially inappropriate. In addition, the timely acquisition of medications can be compromised when prior authorization requirements or other utilization management tools are employed by prescription drug plans. Working through all the steps necessary to obtain coverage for the medication(s) can result in significant delay in delivery and administration. This is in direct conflict with the F425 guidelines, which state that medications should be administered in a timely manner whether prescribed on a routine, emergency, or as-needed basis. Pharmacists and facilities should be aware of these potential conflicts and be prepared to address them as they arise.