Center for Medicaid and State Operations/Survey and Certification Group

Dear Colleague:

I am pleased to send you drafts for comment of revised Guidance to Surveyors of Long Term Care Facilities that will replace guidance at the following current tags:

- F329 – F331 - Unnecessary Drugs (42 CFR 483.25(l)(1) and (2))
- F425 – F432 - The entire Pharmacy Services section (42 CFR 483.60).

This is the second draft of these materials. These products were developed as part of our contract with the American Institutes for Research. Our goals are to update the guidance to surveyors, also known as the interpretive guidelines, and to provide specific information to assist surveyors in making appropriate determinations of severity for deficiencies cited under these Tags. We have consolidated medication and pharmacy Tags as follows:

- Current Tags F329, F330, and F331 will become F329;
- Current Tags F425, F426, and the 42 CFR 483.60(b)(1) portion of F427 will become F425;
- Current Tags F428, F429, and F430 will become F428; and
- Current Tags F431, F432, and the 42 CFR 483.60(b)(2) and (3) portions of F427 will become F431.

The newly developed guidance consists of the following:

- Interpretive Guidelines, Investigative Protocol and Severity Guidance for F329, Unnecessary Medications (Attachment B);
- Interpretive Guidelines, Investigative Protocols and Severity Guidance for F425 (Attachment C), F428 (Attachment D), and F431 (Attachment E), Pharmacy Services.

Comments received for the first drafts were reviewed by the Centers for Medicare & Medicaid Services (CMS) and the expert panels were convened. (Biographical information for each panel is provided in Attachment A.) Based upon the comments, this revised guidance reinforces the necessity of having an effective care delivery process in order to improve outcomes and to reduce risks (to the extent possible) and complications related to medication therapy. It provides
guidance for a surveyor in evaluating how the attending physician and the facility manage the resident’s medication regimen, such as the identification of signs, conditions or symptoms and their causes, and evaluating risks and benefits of interventions in relation to the resident’s prognosis, goals, and choices.

An important focus of the guidance reflects the recognition that all aspects (including indications, dosage, duration, monitoring, and adverse drug consequences) of medication management are important. We are broadening the focus on dosages beyond psychoactive medications to include all categories of medications and we have added guidance on monitoring for effectiveness, and for assessing the possibility that a medication may paradoxically cause or exacerbate symptoms that it was intended to treat or prevent. Thus, when a resident is taking multiple medications, the risks and benefits of any one medication or category of medications must be viewed in relation to the entire medication regimen.

For surveyors, the guidance provides a framework or foundation for medication review rather than attempting to identify all of the details about any one medication or medication category. Please note that Appendix N - Surveyor Procedures for Pharmaceutical Service Requirements in Long Term Care Facilities has been deleted from the State Operations Manual. Instead, information from Appendix N that was judged clinically relevant has been incorporated within the Interpretive Guidelines for Unnecessary Medications and Pharmacy Services. The guidance directs surveyors to consult current professional references as a source of information about medications and their proper usage.

NOTE: We have received several comments regarding the inclusion of psychoactive dosage guidelines. Inclusion of this information is under consideration.

Based upon comments received for the first draft, it is important to note that the regulatory requirements at Unnecessary Drugs and Pharmacy Services have not changed, and we do not anticipate any changes will be needed to the regulations as a result of implementation of the Part D regulations. We are not soliciting comments regarding Part D as part of this mail out. If you have questions on Part D, please contact Tracey McCutcheon, with the CMS Center for Medicare Management, at 410-786-6715, or via email at tracey.mccutcheon@cms.hhs.gov.

We are providing a 45 day comment period for review of the draft materials. We have enclosed a copy of the current scope and severity grid that includes the letters for each grid box and the definitions of each severity level. The scope and severity grid is for your assistance in reviewing the new materials and is not out for comment. Please provide comment on these materials to our contractor by October 21, 2005. You may reply via regular mail addressed to:

Nancy Matheson, Ph.D.
Project Director
American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007
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You may also reply via email to nmatheson@air.org. Please organize your comments by attachment and page number in order to compare your comment to the text to which you are referring. If you have any questions about this mailout, please contact Dr. Matheson at 202-403-5050. We look forward to your comments on these drafts as we proceed with this project to improve our guidance to surveyors.

Sincerely,

/s/

Thomas E. Hamilton
Director

Attachments
### Severity Grid for Rating Nursing Home Deficiencies

<table>
<thead>
<tr>
<th>Severity</th>
<th>Isolated</th>
<th>Pattern</th>
<th>Widespread</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Jeopardy to Resident Health or Safety</td>
<td>J</td>
<td>K</td>
<td>L</td>
</tr>
<tr>
<td>Actual Harm That Is Not Immediate Jeopardy</td>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
<tr>
<td>No Actual Harm with Potential for More than Minimal Harm That Is Not Immediate Jeopardy</td>
<td>D</td>
<td>E</td>
<td>F</td>
</tr>
<tr>
<td>No Actual Harm with Potential for Minimal Harm</td>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

**Level 4: Immediate Jeopardy to resident health or safety. (J, K, L)**
Noncompliance that results in immediate jeopardy, a situation in which immediate corrective action is necessary because the facility’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.

**Level 3: Actual Harm that is not Immediate Jeopardy. (G, H, I)**
Noncompliance that results in a negative outcome that has compromised the resident’s ability to maintain and/or reach his/her highest practicable physical, mental, and psychosocial well-being.

**Level 2: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy. (D, E, F)**
Noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential, (not yet realized) to compromise the resident’s ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being.

**Level 1: No Actual Harm with the potential for minimal harm. (A, B, C)**
A deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

**NOTE:** The Severity and Scope Grid is included to assist your review and is not for comment.
ATTACHMENT A

REGULATORY TAG 329—UNNECESSARY MEDICATIONS EXPERT PANEL

BIOGRAPHIES

• **Tom Clark, RPh, MHS,** is the Director of Policy and Advocacy with the American Society of Consultant Pharmacists and has over 25 years of experience in the pharmacy field. Mr. Clark has made numerous presentations at state and national meetings of pharmacists, health professionals, and consumers. In addition, he is currently serving as an expert on several panels that focus on quality of care in nursing homes and long-term care facilities.

• **Loriann DeMartini, PharmD,** is Chief of the Pharmaceutical Consultant Unit for the California Department of Health Services Licensing and Certification Program. She is responsible for development of state regulations and legislative policies, supervision of statewide field pharmaceutical consultants and serving as a liaison with advocacy organizations and State and Federal governmental agencies. She has approximately 20 years of experience in long term and acute care patient services including psychiatric and alcohol and drug dependence. She has been a speaker at numerous national, regional and statewide CMS training sessions, as well as state survey agencies and advocacy and professional organizations. She is a faculty member for CMS Basic Hospital Survey training and the American Society of Aging.

• **Sarah Greene Burger, RN-C, MPH, FAAN,** is the former Executive Director of The National Citizens’ Coalition for Nursing Home Reform (NCCNHR). In that capacity and as Associate for Program and Policy, she helped build a coalition that focused Congressional attention on important consumer issues: reducing physical and chemical restraint use and malnutrition and dehydration. In 1997, she brought NCCNHR’s consumer minimum staffing standard to a consensus meeting called by the John A. Hartford Institute for Geriatric Nursing, New York University. This minimum standard with enhancements and confirmed by the Center for Medicare and Medicaid Services research has now been recommended for nursing homes by the 2004 IOM report, “Keeping Patients Safe.” She continues to work on developing and implementing policy on a range of issues including nurse-aid training, nurse staffing, resident assessment and care planning. Ms. Burger has authored many consumer materials and guides and co-authored two nursing home consumer books. Currently, she is also the coordinator for the Hartford Institute’s Coalition of Geriatric Nursing Organizations, whose 20,000 nurses seek to improve the quality of care and life for elders wherever they receive their care.

• **Jeanne Jackson, MD,** is a Geriatric Psychiatrist with Geriatric and Adult Psychiatry, LLC, a provider of psychiatric services to the community, local nursing homes, and assisted living facilities. Dr. Jackson is also the Medical Director for the Alzheimer’s Resource Center in Southington, CT as well as Assistant Clinical Professor at the Yale University School of Medicine. From 1999-2002, she chaired the Clinical Practice Committee of the American Association of Geriatric Psychiatry. In addition, Dr. Jackson speaks nationally on issues of aging, long-term care, dementia, geriatric depression, and behavior management.

• **Kathleen O’Brien Johnson, RN,** has served in her current position as a Nurse Surveyor with the State of Maryland Department of Health and Mental Hygiene for over four years. In addition, she has over seven years of experience in nursing, including experience in medical-surgical nursing, critical care nursing, and orthopedics. She belonged to the Phi Theta Kappa
Society during her years at Anne Arundel Community College where she earned associate degrees in Nursing and Fine Art.

- **James E. Lett II, MD, CMD,** is a full time post-acute and long-term care physician as a member of the Sutter Medical Group, a large multi-specialty group in Sacramento, CA. With over 20 years experience as a skilled nursing facility medical director, Dr. Lett currently serves as medical director for several facilities in the Sacramento area. He holds a Certificate in Added Qualifications (CAQ) in Geriatrics and is a Certified Medical Director (CMD) in addition to his certification by the American Board of Family Practice. Dr. Lett has spoken and written on multiple long term care subjects over the years. He is active with the American Medical Directors (AMDA), having served in multiple roles including president in 2003-2004.

- **Evvie Munley, BSW,** has served as Senior Health Policy Analyst with the American Association of Homes and Services for the Aging (AAHSA) since 1986, focusing on regulatory analysis and quality-related issues for long-term care facilities, including survey, certification, and enforcement, life safety, and end-of-life. Ms. Munley serves as AAHSA’s primary liaison to the Centers for Medicare and Medicaid Services and other federal agencies having related regulatory authority or policy-development interest in nursing facilities. Her prior experience includes six years as a social worker working with individuals with developmental disabilities, and six years in the field of licensing and inspections for facilities for the developmentally disabled.

- **Janet Myder, MPA,** is an independent long-term care consultant specializing in nursing facility survey, certification and enforcement policy. In early 2005 she completed an 18-year tenure as Director of Regulatory Systems with the American Health Care Association (AHCA) where she managed regulatory analysis and related policy development in the areas of nursing facilities’ participation in Medicare and Medicaid; survey and enforcement; and fire safety. Ms. Myder served on numerous advisory and technical expert panels convened by the Centers for Medicare and Medicaid Services (CMS) to develop survey and enforcement policies, protocols, and interpretive guidance; revise surveyor training; improve informal dispute resolution; reduce restraints use; and implement special initiatives. She represented AHCA for six years to the U.S. Food and Drug Administration convened Hospital Bed Safety Work Group (HBSW) and guided the development of the HBSW Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care and Home Care Settings. Prior to her public policy career, Ms. Myder practiced physical therapy in hospitals, home health, and physician office settings and served four years as administrator of the physical medicine department in a 300-bed community hospital.

- **Carla Saxton, RPh, CGP,** is a certified geriatric pharmacist and currently serves as Assistant Director of Policy and Advocacy with the American Society of Consultant Pharmacists. She has worked in a variety of pharmacy settings including retail pharmacy and long-term care dispensing, consulting, and IV services. She currently serves as Vice-Chairperson for the National Coordinating Council for Medication Error Reporting and Prevention, while also participating in the Pharmacy Career Information Clearinghouse, National Council for Prescription Drug Programs’ Long-Term Care Work Group, and the Professional Services Technical Advisory Coalition.

- **Todd Semla, MS, PharmD, BCPS, FCCP,** is a Clinical Pharmacy Specialist for the Department of Veterans Affairs Pharmacy Benefits Management Program. He is also an Associate Professor in the Department of Psychiatry and Behavioral Sciences at Northwestern University’s Feinberg School of Medicine. Dr. Semla serves as the Secretary of the American
Geriatrics Society and is the Section Editor for “Drugs and Pharmacology” in the Journal of the American Geriatrics Society.

- **Mark Sey, RPh, CGP, FASCP**, is Director of Pharmacy Services for Lodi Memorial Hospital, a non-profit, community hospital which includes care for a significant population of long-term, sub-acute patients. Previously, he was the owner-operator of Mark Sey and Associates, an independent pharmacy consulting practice servicing acute care, long-term care, and assisted living residences. Additionally, Mr. Sey was the lead pharmaceutical consultant with the California Department of Health Services, the agency responsible for reviewing the quality of patient care in all licensed health facilities in California. Mr. Sey served as the 2001-2002 President of the American Society of Consultant Pharmacists.

- **Rick Shannon, RPh**, is a researcher and teacher at the Centers for Health Systems Research and Analysis, which developed the Quality Indicators for nursing homes for CMS. He is also an analyst for the Long Term Care Institute, working with CMS to review quality of care and life in nursing homes. Mr. Shannon has been a consultant to the Wisconsin State survey agency for 22 years, and has been a clinical instructor at the University of Wisconsin School of Pharmacy for over a decade. His areas of expertise include LTC pharmacy, pain management, psychotropic drug use, and Quality Improvement.
REGULATORY TAG 425/F428/F431—PHARMACY SERVICES EXPERT

PANEL BIOGRAPHIES

- **Cynthia Best, RN, BSN, BC**, serves as the Director of Clinical Support and Compliance Officer of Provena Senior Services. In this position, Ms. Best provides clinical, survey, policy, compliance and education expertise to the Provena Senior Services nursing facilities. Ms. Best has over 10 years experience in long term care and has been a Director of a hospital based SNF unit, a Program Director for Adult Day Care, a Medicare Case Manager, and a MDS Coordinator. Ms. Best is a board certified gerontological nurse and is currently earning her master’s degree in Health Administration.

- **Tom Clark, RPh, MHS**, is the Director of Policy and Advocacy with the American Society of Consultant Pharmacists and has over 25 years of experience in the pharmacy field. Mr. Clark has made numerous presentations at state and national meetings of pharmacists, health professionals, and consumers. In addition, he is currently serving as an expert on several panels that focus on quality of care in nursing homes and long-term care facilities.

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- **Doug Englebert, RPh, MBA**, is a pharmacist in the Wisconsin Department of Health and Family Services, Bureau of Quality Assurance. Doug has practiced in a wide range of settings including acute care, managed care and long-term care. Currently, Doug provides leadership communicating, setting and enforcing pharmacy standards by conducting health care licensing and certification surveys, providing consulting services, and conducting training for surveyors and providers in the State of Wisconsin.

- **Fred Evans, RPh, FASCP, CGP**, is a Clinical Services Director with NeighborCare in Annapolis Junction, Maryland. Mr. Evans has over 40 years experience as a Pharmacist and is the immediate past president of the MD-Chapter of the American Society of Consultant Pharmacists.

- **Evvie Munley, BSW**, has served as Senior Health Policy Analyst with the American Association of Homes and Services for the Aging (AAHSA) since 1986, focusing on regulatory analysis and quality-related issues for long-term care facilities, including survey, certification, and enforcement, life safety, and end-of-life. Ms. Munley serves as AAHSA’s primary liaison to the Centers for Medicare and Medicaid Services and other federal agencies having related regulatory authority or policy-development interest in nursing facilities. Her prior experience includes six years as a social worker working with individuals with developmental disabilities, and six years in the field of licensing and inspections for facilities for the developmentally disabled.
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ATTACHMENT B

F329 UNNECESSARY MEDICATIONS GUIDANCE
**INTENT:** (F329) 42 CFR 483.25(l)

The intent of this requirement is that each resident’s entire drug/medication regimen be managed and monitored to achieve the following goals:

- Each resident receives only those medications, in appropriate doses for the appropriate duration, clinically necessary to treat the resident’s assessed condition(s);
- Non-pharmacologic interventions (such as behavioral interventions) are considered and used instead of, or in addition to, medication when indicated;
- The medication or medication combination helps promote or maintain the resident’s highest practicable physical, functional, and psychosocial well-being, as identified by the resident and/or legal representative in collaboration with the facility staff;
- Risks for adverse consequences or negative outcome(s) as a result of the medication(s) are minimized; and
- If the resident experiences a decline or newly emerging or worsening symptoms, the change is recognized promptly, the medication regimen is evaluated as a potential contributing or causative factor, and changes are made as appropriate.

**NOTE:** This guidance applies to all categories of medications including antipsychotic medications.

Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications” instead of “drugs,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

**NOTE:** The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

**DEFINITIONS**

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

- “Adverse consequences” – An effect that is due to or associated with a medication and that is manifested as an unpleasant symptom, or that impairs or causes a decline in an individual’s health, physical condition, or functional or psychosocial status. It may include various types of adverse drug reactions and interactions.
• “Adverse drug reaction (ADR)” – A type of adverse consequence that is a secondary effect of a medication, which is undesirable and different from the helpful and therapeutic effects of the medication. It may include a side effect, hypersensitivity, idiosyncratic response, toxic reaction or medication interaction.

• “Anticholinergic side effects” – Effects of a medication that oppose or inhibit the activity of the parasympathetic (cholinergic) nervous system to the point of causing problematic or undesirable symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, or hallucinations.

• “Behavioral interventions” – A type of non-pharmacological approach to try to influence or redirect behavior; for example, by talking with the individual, restructuring the environment, discussing and enforcing limits on acceptable behavior, or various psychosocial and activities interventions.

• “Clinically significant” – Effects, results, or consequences that materially affect or are likely to affect an individual’s physical, functional, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

• “Distressed behavior” – Behavior that reflects individual discomfort or emotional strain, which may lead to harm to self or others. It may present as apathetic or withdrawn behavior, pacing, moaning, or as verbal or physical actions such as: cursing, hitting, kicking, pushing, scratching, tearing things, grabbing, or sexual contact without consent.

• “Dose” – The total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

• “Duplicative therapy” – Multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

• “Gradual Dose Reduction (GDR)” – The stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

• “Duration” – The total length of time the medication is being received.

• “Extrapyramidal Side Effects” – Signs and symptoms related to impairment of the extrapyramidal nervous system, such as tremors, postural unsteadiness, slowness of movement, expressionless face, drooling, shuffling gait, akathisia (physical
symptoms of restlessness or constant motion, such as inability to sit still, fidgeting, pacing, rocking) or rigidity of muscles in the limbs, neck, and trunk.

- “Indications for use” – The identified, documented clinical rationale for administering a medication based upon an assessment of the resident’s condition and therapeutic goals and on manufacturer’s recommendations.

- “Medication Interactions” – The impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may result in alterations of absorption, effectiveness, duration of therapeutic effect, circulatory transport, inactivation, excretion, or potential for adverse consequences.

- “Monitoring” – The ongoing collection and analysis of information (including observation and diagnostic test results, etc.) and comparison to baseline data in order to: a) ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal and detection of any complications or adverse consequences of the condition or of the treatments; and b) support decisions about modifying, discontinuing, or justifying the continuation of any intervention.

- Non-pharmacological interventions – Approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident’s condition and/or behavior. Examples of such approaches include alternate or complementary therapies to address pain, identifying and reducing environmental and psychosocial stressors, basing daily care on customary or life-long routines, encouraging involvement in person-appropriate activities, using sleep-hygiene techniques, etc.

- “Psychotherapeutic medication” – Any medication traditionally identified as a psychotrophic (e.g., antipsychotics, anxiolytics, antidepressants, central nervous system stimulants, sedatives, and hypnotics) or any medication prescribed with the intent to manage or treat psychiatric disorders or distressed behavior or mood (such as mood stabilizers, anti-manic medication, cognitive enhancers, anti-convulsants).

- “Side Effect” – An expected, known reaction that occurs with a predictable frequency and is less intense or problematic than an ADR. Side effects of minimal impact or duration do not necessarily constitute adverse consequences. Consideration of side effects may be a key factor in selecting particular medications.

- “Tardive Dyskinesia” – A syndrome (often medication-related and sometimes irreversible) that affects parts of the nervous system associated with movement. It is characterized by abnormal, involuntary movements, such as recurrent oral facial movements, lateral movements of the tongue, tongue thrusting, chewing, or
lateral jaw movements, frequent blinking, brow arching, grimacing, and lip smacking. Although commonly associated with antipsychotic medications, the syndrome may occur with various other medications (such as metoclopramide) and medication combinations.

OVERVIEW

Medications are an integral part of the care provided to residents of nursing facilities. Medications are administered to try to achieve various outcomes, such as curing an acute illness, diagnosing a disease or condition, arresting or slowing a disease process, reducing or eliminating symptoms, or preventing a disease or symptom.

A 2000 study of 33,301 nursing facility residents found an average of 6.7 medications used per resident, with 27 percent of residents taking nine or more medications. A 2001 study reported that of 693,000 residents who received antipsychotics, 58 percent either lacked appropriate indications for use or received doses exceeding maximum recommended dosage levels, including duplicative therapy.

Proper medication selection and prescribing (including dose, duration, and type of medication(s)) may stabilize or improve a resident’s outcome, quality of life and functional capacity. But any medication—or the use of a medication without adequate indications, in excessive dose, for an excessive duration, or without adequate monitoring—may increase the risk of adverse consequences such as medication interactions, depression, confusion, immobility, falls, and hip fractures.

Intrinsic factors including physiological changes accompanying the aging process, multiple comorbidities, and certain medical conditions may affect the absorption, distribution, metabolism or elimination of medications from the body and may also increase an individual’s risk for adverse consequences.

The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacologic approaches, are determined by assessing the resident’s underlying condition and current signs and symptoms. This includes, where possible, the identification of the root cause(s), since a diagnosis alone may not warrant treatment with medication.

Many residents receive orders for medications from several practitioners, for example, attending and on-call physicians, consultants, and nurse practitioner(s). Multiple prescribers can increase the resident’s chances of receiving unnecessary medications. It is important that the facility clearly identify who is responsible for prescribing and identifying the indications for use of medication(s), for providing and administering the medication(s), and for monitoring the resident for the effects and potential adverse consequence of the medication regimen. This is also important when care is delivered or ordered by diverse sources such as consultants, providers or suppliers (e.g., hospice or dialysis programs).
Several mechanisms exist to warn practitioners about risks associated with medications. The Food and Drug Administration (FDA) requires manufacturers’ labeling to include warnings about serious adverse reactions and potential safety hazards, and what to do if they occur. The FDA requires manufacturers to warn about newly identified serious medication hazards—particularly those that may lead to death or serious injury—regardless of whether causation has been proven. Also, the FDA may require specific warnings if a medication is commonly prescribed for a disease or condition that is not included in the “Indications and Usage” section of the labeling (so-called “off-label” use or unapproved use) and such usage is associated with a serious risk or hazard. The FDA may require manufacturers to place special problems in a prominently displayed box (so-called boxed or “black box” warnings). While they usually do not prohibit the off-label uses, the boxed warnings indicate a need to closely evaluate the potential benefits and risks.

Staff and practitioner access to current medication references and pertinent clinical protocols helps to assure safe administration and monitoring of medications. Listings or descriptions of most significant risks, recommended doses, medication interactions, cautions, etc. can be found in widely available, standard references, and computer software and systems that provide up-to-date information. The facility’s consultant pharmacist is a significant source of information about medications.

Clinicians often rely upon clinical standards of practice and clinical guidelines established by professional groups. Some of the recognized clinical resources available for understanding the overall treatment and management of medical problems and symptoms and medication consequences and precautions include the:

- American Geriatrics Society (www.americangeriatrics.org and www.geriatricsatyourfingertips.org);
- American Medical Directors Association (www.amda.com);
- American Society of Consultant Pharmacists (www.ASCP.com);
- Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov;
- American Association of Geriatric Psychiatry www.aagp.org;
- Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives www.medqic.org;
- Association for Practitioners in Infection Control and Epidemiology www.apic.org;
• Society for Healthcare Epidemiologists of America (SHEA) Long-Term Care Committee, www.shea-online.org;

• U.S. Department of Health and Human Services, Food and Drug Administration website www.fda.gov/medwatch/safety.htm; and

• U.S. Department of Health and Human Services, National Institute of Mental Health website, which includes publications and clinical research information www.nimh.nih.gov.

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Although these guidelines focus generally on the older adult resident, adverse consequences can occur in anyone at any age, and the requirements regarding indications for use, dose, duration, monitoring, adverse consequences, and initiation of antipsychotic medications are applicable to residents of all ages. Special considerations may apply to gradual dose reduction and tapering medications in the younger population.

MEDICATION MANAGEMENT

This guidance is intended to help the surveyor determine whether the facility has a system for medication management that:

• Promotes selection of medications(s) based on assessing relative benefits and risks to the individual resident;

• Promotes evaluation of a resident’s signs and symptoms, in order to identify the underlying cause(s), including adverse consequences of medications;

• Promotes the use of medications in doses and for the duration appropriate to each resident’s clinical conditions, age, and underlying causes of symptoms;

• Promotes the use of non-pharmacologic interventions to minimize the need for medications, permit use of the lowest possible dose, or allow medications to be discontinued, to the extent possible; and

• Promotes the monitoring of medications for side effects and efficacy; especially, medications associated with a significant risk for adverse consequences.

Medication management is based in the care process and includes recognition or identification of the problem/need, assessment, diagnosis/cause identification, management/treatment, monitoring, and revising interventions, as warranted. The
attending physician plays a key role in developing, monitoring, and modifying the medication regimen in conjunction with the residents and/or their representatives, and other professionals and direct care staff. Optimizing therapeutic benefits and preventing adverse consequences should be paramount considerations both before and after initiating medication therapy.

Members of the interdisciplinary team participate in the care process as they identify, assess, address, monitor, and communicate the resident’s needs and changes in condition. This includes: a) being alert to individual needs and changes in condition, b) supporting residents who have limited ability to understand, communicate, or make decisions, and c) considering the resident’s religious beliefs, and cultural and personal preferences, when selecting medication and non-pharmacological interventions.

The resident’s clinical record documents and communicates to the entire team the basic elements of the care process. Information about aspects of the care process related to medications may be found in various locations within the record, such as: discharge summary(ies) and transfer notes, progress notes and interdisciplinary notes, history and physical examination, Resident Assessment Instrument (RAI), plan of care, laboratory reports, professional consults, medication orders, Medication Regimen Review reports (MRR), Medication Administration Records (MAR), etc.

**Resident Choice** – A resident has the right to make informed choices about accepting or declining care and treatment. The physician and facility staff can help the resident exercise this right by discussing with the resident and/or the legal representative the resident’s condition, treatment options, related risks and benefits, expected outcomes, and possible consequences of refusing treatment. If a resident declines treatment, the facility staff and physician collaborate to address the resident’s concerns and offer appropriate alternatives; for example, offering the medication at another time or in another dosage form. This does not imply that the facility must necessarily follow requests from residents and/or legal representatives to institute, continue, increase, or avoid specific medications, if such requests would endanger the health and safety of the resident or other persons (for example, the medication is not indicated or abrupt medication withdrawal would be likely to precipitate delirium).

**Advance Directives** – A resident may have written or verbal directions related to treatment choices (or a decision has been made by the resident’s surrogate or representative) in accordance with state law. An advance directive is a means for the resident to communicate his or her wishes, which may include withdrawing or withholding medications. The facility is still responsible for giving treatment, support, and other care that is consistent with the resident’s condition and applicable care instructions.

**NOTE:** Choosing not to be resuscitated (reflected in a “Do Not Resuscitate” (DNR) order) indicates that the resident should not be resuscitated if respirations and/or cardiac function cease. A DNR order by itself does not indicate that the resident has declined other appropriate treatment and services.
Under these regulations, medication management includes consideration of:

I. Indications for use of the medication (including initiation of antipsychotic medications);

II. Monitoring for efficacy and adverse consequences;

III. Appropriate dose, duplicative therapy, and gradual dose reduction for antipsychotic medications;

IV. Appropriate duration; and

V. Prevention, identification, and response to adverse consequences.

I. Indications for Use of Medication (including Initiation of an Antipsychotic Medication)

An evaluation of the resident helps to identify his/her needs, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms and test results; and to select pertinent interventions. As part of the evaluation, gathering and analyzing information helps define clinical indications and provide baseline data to enable subsequent monitoring. The evaluation also clarifies:

- Whether the target symptoms and/or related causes warrant medication therapy;
- Whether non-pharmacologic interventions may be relevant;
- Whether a particular medication is pertinent to managing the symptom or condition; and
- Whether intended or actual benefit is sufficient to justify the potential risk(s) or adverse consequences associated with the selected medication, dose, and duration.

If a medication is prescribed for PRN (as needed) use, the circumstances for its use should be clearly delineated. Vague orders, such as “PRN agitation” provide insufficient direction.

The information gathered during the evaluation is essential to:

- Develop a comprehensive care plan that reflects the goals for giving the medication and the parameters for monitoring;
- Optimize medication therapy and minimize potential adverse consequences;
- Establish parameters for evaluating the ongoing need for the medication; and
• Verify or differentiate the underlying diagnoses (or the underlying causes) of signs and symptoms.

The content and extent of the evaluation may vary with the situation and may employ various assessment instruments and diagnostic tools. Examples of information to be considered and evaluated may include, but are not limited to, the following:

• An appropriately detailed evaluation of physical, psychosocial, and functional status, including comorbid conditions and pertinent psychiatric symptoms and diagnoses and a description of resident complaints, symptoms, and signs (including the onset, scope, frequency, intensity, precipitating factors, and other important features);

• Each resident’s goals and preferences;

• Allergies to medications and foods and potential for medication interactions;

• A history of prior and current medications and non-pharmacological intervention (including therapeutic effectiveness and any adverse consequences);

• Recognition of the need for end-of-life or palliative care;

• The refusal of care and treatment, including the basis for the refusal, and the identification of pertinent alternatives; and

• Whether an appropriate indication for a medication no longer exists.

NOTE: The Resident Assessment Protocols (RAPs), an integral part of the comprehensive resident assessment, help identify some possible categories of causes of various symptoms including: behavioral symptoms of distress, delirium, and changes in functional status. Refer to 42 CFR 483.20 and the Minimum Data Set (MDS) and RAPs.

Circumstances that could warrant evaluation may include:

• Admission or re-admission;

• A clinically significant change in condition/status;

• A new, persistent, or recurrent clinically significant symptom or problem;

• A worsening of an existing problem or condition;

• An otherwise unexplained decline in function or cognition;
• A non-specific symptom that is not otherwise attributable to an underlying physical or functional cause;

• A new medication order or renewal of orders;

• An irregularity identified in the consultant pharmacist’s monthly medication regimen review.

Specific considerations related to these circumstances may include the following:

• **Admission** – Some residents may be admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued. It is expected that the attending physician, consultant pharmacist, and staff subsequently evaluate the resident’s clinical condition, risks, existing medication regimen, and related factors in order to determine if continuing the medication is justified. It is generally not sufficient to continue such medications simply because they were prescribed by a specialist or begun in another care setting, such as the hospital, unless there is a clearly documented rationale. If the indications for continuing the medication are unclear, or if the resident’s symptoms could represent a clinically significant adverse consequence, additional consideration of the rationale for the medication(s) is warranted.

• **New medication order as an emergency measure** – When a resident is experiencing an acute medical problem or psychiatric emergency (e.g. the resident’s behavior poses an immediate risk to the resident or others), medications may be required. In these situations, it is important to identify and address the underlying causes of the problem or symptoms. Once the acute phase has stabilized, the staff and practitioner should consider whether medications are still relevant. Subsequently, the medication should be reduced or discontinued as soon as possible or the clinical rationale for continuing the medication or dose be documented.

When psychotherapeutic medications are used as an emergency measure, adjunctive approaches, such as behavioral management techniques, should always be considered and implemented as appropriate. Longer term management options should be discussed with the resident and/or legal representative. Some states may have laws or regulations regarding use of such medications.

• **Psychiatric disorders or distressed behavior** – Distressed behaviors such as psychosis and aggression are symptoms with underlying causes. As with all symptoms it is important to seek the underlying cause, either before or while treating the symptom. Examples of potential causes include:

  o Chronic psychiatric illness such as schizophrenia or schizoaffective disorder;
Acute psychotic illness such as brief reactive psychosis;
- Substance intoxication or withdrawal;
- Neurological illnesses such as Huntington’s disease or Tourette’s disorder;
- Medical illnesses such as Alzheimer’s disease, Lewy body disease, Vascular dementia or Frontotemporal dementia; or
- Delirium.

Antipsychotics have specific limited indications; therefore, any use outside of these indications should be supported with clearly documented clinical rationale. See Table I below in these guidelines for key issues related to indications for use of antipsychotic agents, monitoring, and adverse consequences.

II. Monitoring

The key objectives for monitoring the use of medications are to track progress towards the therapeutic goal(s) and to detect emergence or presence of any adverse consequences. Effective monitoring relies upon understanding the indications and goals for using the medication (including relevant baseline information), the criteria for evaluating its benefits, and recognizing and evaluating adverse consequences. Monitoring parameters are based on the resident’s condition, the nature of the medication being used and its associated risks, individualized therapeutic goals, and the potential for clinically significant adverse consequences.

There is published evidence that adverse consequences related to medications are common enough to warrant serious attention and close monitoring. For example, a study published in 2005 reported that 338 (42%) of 815 adverse drug events were judged preventable, and that common omissions included inadequate monitoring and either lack of response or a delayed response to signs or symptoms or laboratory evidence of medication toxicity.

Sources of information to facilitate defining the monitoring criteria or parameters may include cautions, warnings, and identified adverse consequences from:

- Manufacturers’ package inserts and black-box warnings;
- Facility policies and procedures;
- Consultant pharmacists;
- Clinical practice guidelines or clinical standards of practice;
- Medication references; and
- Clinical studies with evidence, evidence-based medicine, or studies published in medical and/or pharmacy journals.

While monitoring the effectiveness of medications used to address behavioral symptoms is required, facility-adopted behavior monitoring sheets are optional, and other approaches may suffice to permit evaluation of the resident’s progress over time. Examples of tools used for determining baseline status as well as for monitoring may include, but are not limited to:

- Physiological, Cognitive, and functional status:
  - Vital signs
  - Electrocardiograms and rhythm strips
  - Blood sugars
  - Resident Assessment Instrument (RAI)
  - Functional Alzheimer’s Screening Test (FAST) scale
  - Physical Self Maintenance Scale (PSMS)
  - Mini-Mental Status Exam (MMSE)
  - Confusion Assessment Method (CAM)
  - Instrumental Activities of Daily Living Scale (IADL)
  - Abnormal Involuntary Movement Scales (AIMS)

- Mood/Affect
  - Geriatric Depression Scale (GDS)
  - Cornell Depression in Dementia Scale
  - Mania Rating Scale

- Behavior
  - Behavior Rating Scale for Geriatric Patients-Care Dependency Subscale (BGP)
  - Behavioral Pathology in Alzheimer’s Disease Rating Scale (Behave AD)
o Cohen-Mansfield Agitation Inventory (CMAI)

o Neuro-psychiatric Inventory-Nursing Home Version (NPI-NH)

Development of the monitoring plan involves several steps, including:

- **Identifying the essential information and how it will be obtained and reported.** The use of quantitative and qualitative monitoring parameters facilitates consistent and objective collection of information by the facility. It is important to consider who is responsible for obtaining the information, which information should be collected, and how the information will be recorded. The information collection process is dependent on both therapeutic goals and detection of potential or actual adverse consequence as well as consideration of risk factors, such as:
  
  o Medication-medications interactions;

  o Clinical condition (for example renal disease);

  o Medication-food interactions;

  o Black-box warnings; and

  o History of adverse consequences related to a similar medication.

- **Determining the frequency of monitoring.** The frequency of monitoring and the length of time needed to identify therapeutic effectiveness and adverse consequences will depend on factors such as standards of clinical practice, facility policies and procedures, manufacturer’s specifications, nature of the medication, and the resident’s clinical condition. Monitoring involves three aspects:
  
  o Periodic planned evaluation of progress toward the therapeutic goals;

  o Continued vigilance for adverse consequences; and

  o Evaluation of identified adverse consequences.

- **Defining the methods for communicating, analyzing, and acting upon relevant information.** The monitoring process needs to identify who is to communicate with the prescriber, what information is to be conveyed, and when to ask the physician to evaluate and consider modifying the medication regimen.

  It is important to consider whether a resident’s medications are promoting or maintaining a resident’s highest practicable level of function. If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is
essential to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued.

- **Re-evaluating and updating the plan periodically.** The monitoring plan may need modification when the resident experiences changes, such as:
  - Acute onset of signs or symptoms or worsening of chronic disease;
  - Decline in function or cognition;
  - Addition or discontinuation of medications and/or non-pharmacologic interventions;
  - Addition or discontinuation of care and services such as enteral feedings; and
  - Significant changes in diet that may affect medication absorption or effectiveness.

Additional examples of circumstances that may indicate a need to modify the plan include: changes in manufacturers’ specifications, FDA warnings, pertinent clinical practice guidelines, or other literature about how and what to monitor.

**III. Dose, Duplicative Therapy, Gradual Dose Reduction (GDR)**

A practitioner orders medication doses based on factors including the resident’s diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results, input about the resident from the interdisciplinary team, and the nature and therapeutic goals of the medicines being considered or being used. Sometimes, both strength and amount (quantity) of medication determine the dose. The route of administration influences the absorption of medications. For example, the absorption of medications delivered by transdermal patches may be affected by factors including temperature, moisture, and the integrity of the patch; or the flow rate of intravenous solutions affects the amount received at a given time.

The appropriateness of the dose is influenced by the resident’s clinical response and other related factors such as the possible presence of adverse consequences. It should be noted that lab test results such as serum medication concentrations are often only a rough guide to dosing. Significant adverse consequences can occur with “therapeutic” concentrations, and serum concentrations alone may not necessarily indicate a need for dose adjustment.

Duplicate therapy is generally not indicated, unless current clinical standards and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effect. For example, more than one analgesic may be necessary to control varying levels of pain, and multiple medications may be necessary to promote adequate bowel function.
Documentation of the rationale for prescribed doses may be found in various areas of the resident’s clinical record. Along with other information that the facility and practitioner provide, this documentation clarifies why multiple medications from the same pharmaceutical class or therapeutic categories or with similar effects are necessary for a resident, and how benefits and adverse consequences will be, or have been identified. Some examples of these considerations include:

- Using combination products could lead to excessive doses of the product;
- Prolonged use of acetaminophen in addition to acetaminophen with hydrocodone to control pain may lead to toxic effects of acetaminophen;
- Simultaneous use of multiple benzodiazepines could lead to excessive sedation, falls, or other adverse consequences; and
- Use of medications from different therapeutic categories that have similar effects or properties, such as anticholinergic effects, may increase the potential for compounded or more severe effects, for example, if medications such as oxybutynin and hydroxyzine are being given simultaneously.

**Tapering of a Medication Dose/ Gradual Dose Reduction (GDR)**

Tapering of any medication dose may be indicated when, for example, the resident’s clinical condition has improved and/or declined; the medication no longer benefits the resident; and/or the continued use of a medication may be considered an excessive dose. For example, cough, cold, and allergy medications that are given to address acute upper respiratory symptoms should be discontinued after the acute episode has resolved, unless there is a valid clinical indication for prolonged use. For some medications, gradual tapering rather than an abrupt cessation may be necessary; for example, to avoid withdrawal symptoms from hypnotics or opioid analgesics. When any medication is being tapered, the resident should be monitored closely for both exacerbation of symptoms or evidence of withdrawal symptoms.

The regulation at F329 requires that a resident who is receiving an antipsychotic medication should receive behavioral interventions and a GDR of the antipsychotic medications, unless clinically contraindicated, in an effort to discontinue the antipsychotic medications. Some conditions (such as delirium and brief reactive psychosis) do not generally require long-term use of antipsychotics. Many longer term psychiatric and behavioral problems can be adequately treated, and good symptom control maintained, with a lower maintenance dose of psychotherapeutic medications.

Reasons to discontinue or not attempt tapering or GDR (such as end-of-life care) should be documented including the clinical rationale and any adverse effects on the resident from previous attempts at GDR. Examples include:

- The resident has a “specific condition” as listed in Table I and:
Has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations) which have been stabilized with a maintenance dose of an antipsychotic medication without incurring significant side effects; or

A gradual dose reduction has been attempted at least twice in one year, and those attempts resulted in the return of symptoms for which the medication was prescribed to a degree that the gradual dose reduction had to be stopped or a higher dose was needed to control symptoms; or

The resident’s physician provides clinical justification for why the continued use of the medication and the dose of the medication is clinically appropriate, including:

- A diagnosis with a description of symptoms;
- A discussion of the differential psychiatric and medical diagnosis (e.g., why the resident’s behavioral symptom is thought to result from dementia with associated psychosis and/or agitated behaviors, and not from an underlying medical condition or a psychosocial or environmental stressor);
- A justification for the choice of a particular treatment(s), and
- A discussion of why the present dose is necessary to manage the resident’s symptoms.

IV. Duration

Many conditions require treatment for extended periods, while others (for example, nausea and/or vomiting, acute pain, psychiatric or behavioral symptoms) may resolve and no longer require medication therapy. Therefore, periodic re-evaluation of the medication regimen is necessary to determine whether prolonged or indefinite use of a medication is indicated.

The clinical rationale for continued use of a medication(s) may have been demonstrated in the clinical record, or the staff and practitioner may present pertinent clinical reasons for the duration of use. Common considerations for appropriate duration may include:

- A medication initiated as a result of a time-limited condition (for example, delirium, pain, infection, nausea and vomiting, cold and cough symptoms, or itching), is then discontinued when the condition has resolved or there is documentation indicating why continued use is still relevant. Failure to review for whether the underlying cause has resolved may lead to excessive duration.
- A medication is discontinued when indicated by the practitioner’s order or by
facility stop order policy, unless there is documentation of the clinical justification for its extended use. A medication administered beyond the stop date established in the physician’s order, or by facility policy, without evidence of clinical justification for continued use of the medication may be considered excessive duration.

V. Adverse Consequences

Any medication can cause adverse consequences. Some adverse consequences occur quickly or abruptly, while others are more insidious and develop over time. Adverse consequences may become evident shortly after the initiation of a medication, a change in dose, or after the medication is discontinued. A medication’s recognized safety, tolerability, ease of dosing, and potentially troublesome medication–medication interactions are important considerations before prescribing a medication. Although a resident may have an unanticipated reaction to a medication that is not always preventable, many ADRs can be anticipated, minimized, or prevented. Some adverse consequences may be avoided by following relevant clinical guidelines and a manufacturer’s specifications for use, dose, and duration of the medication, by defining appropriate indications for use, and determining that the resident:

- Has no known allergies to the medication;
- Is not taking other medications, dietary supplements, herbal remedies, or foods that would be incompatible with the prescribed medication; and
- Has no condition, history, or sensitivities that would preclude use of that medication.

Published studies have sought to identify the frequency, severity, and preventability of adverse consequences. Neuropsychiatric, hemorrhagic, gastrointestinal, renal/electrolyte abnormalities and metabolic/endocrine complications were the most frequent of overall and preventable adverse consequences identified in two of the studies. Specifically, a study of 18 community-based nursing homes reported that 50 percent (276/546) of the adverse consequences were considered preventable and that 72 percent of those considered as fatal, life-threatening, or serious were preventable. A second study of two academic-based nursing homes reported that inadequate monitoring, failure to act on the monitoring, and errors in ordering, including wrong dose, wrong medication, and medication–medication interactions were the most frequently associated causes for the preventable adverse consequences.

The risk for adverse consequences increases with both the number of regular medications being taken and with medications from specific medication classes, such as anticoagulants, diuretics, antipsychotics, anti-infectives, and anticonvulsants. See Tables I and II for additional classes of medications that are associated with frequent or severe adverse consequences. The consequences of an ADR can range from minimal harm to functional decline, hospitalization, permanent injury, and death.
Delirium (i.e., acute confusional state) is a common adverse consequence. In many facilities, more than 50% of the residents have dementia. Residents who have dementia may be more sensitive to medication effects and may be at greater risk for delirium. Delirium may result from treatable underlying causes including medical conditions and the existing medication regimen. The presence of delirium is associated with higher morbidity and mortality. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late stages of dementia. Careful observation of the resident (including mental status and level of consciousness), review of the potential causes for the mental changes (e.g., ADRs, fluid and electrolyte imbalance, infections), and appropriate and timely management of delirium are essential.

ENDNOTES


TABLE I

MEDICATION ISSUES OF PARTICULAR RELEVANCE TO LONG-TERM CARE

This table lists alphabetically, examples of some categories of medications that are likely to cause clinically significant adverse consequences in elderly individuals; medications with limited indications for use, those requiring precautions in selection or use, or those requiring specific monitoring.

NOTE: This table is not all inclusive and does not address all issues related to medication use, such as dosages. Medications other than those listed in this table may present significant issues related to indications, dosage, duration, monitoring, or potential for clinically significant adverse consequences. Refer to an authoritative source for detailed medication information related to issues such as dosage, monitoring or adverse consequences, that you are investigating.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics</td>
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<tr>
<td>Acetaminophen</td>
<td><strong>Dosage / Adverse Consequences</strong>&lt;br&gt;• Daily doses greater than 4 grams/day from all sources (alone or as part of combination products) may increase risk of liver toxicity</td>
</tr>
<tr>
<td></td>
<td><strong>Monitoring</strong>&lt;br&gt;• For doses above 4 gm/day, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks</td>
</tr>
<tr>
<td>Meperidine (Demerol)</td>
<td><strong>Indications</strong>&lt;br&gt;• Not an effective oral analgesic in doses commonly used in the elderly</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• Use (oral or injectable) may cause confusion, respiratory depression even with therapeutic analgesic doses</td>
</tr>
<tr>
<td></td>
<td>• Active metabolite of Meperidine (normerperidine) accumulates with repeated use and has been associated with seizures</td>
</tr>
<tr>
<td>Nonsteroidal anti-inflammatory drugs (NSAIDs) (ibuprofen, naproxen, diflunisal, ketorolac, diclofenac, indomethacin, piroxicam, tolmetin, and)</td>
<td><strong>Indications</strong>&lt;br&gt;• NSAID and COX-2 inhibitor use should be reserved for conditions and symptoms for which lower risk analgesics (e.g., acetaminophen) have either failed or are not clinically indicated, or situations where the medications are effective and benefits are considered to warrant the risks</td>
</tr>
<tr>
<td></td>
<td><strong>Interactions</strong></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
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| meclofenamate) and COX-2 inhibitors (celecoxib) | • Aspirin may reduce the protective effects of COX-2 inhibitors on the gastrointestinal (GI) tract  
• Use NSAIDs and COX-2 inhibitors with caution in anyone who is receiving aspirin > 325 mg/day, other platelet inhibitors (i.e., ticlopidine (Ticlid), clopidogrel (Plavix), dipyridamole (Persantine)), or anticoagulants |
|                            | **Adverse Consequences**                                                                                                                                                                                                 |
|                            | • Use with caution in anyone with a prior history of, or increased risk for, gastrointestinal bleeding  
• Use with caution in anyone who is receiving warfarin, heparin, or other anticoagulants; monitor closely for bleeding  
• Any NSAID may cause or worsen renal failure, increase blood pressure, exacerbate heart failure, or reduce cardio-protective effects of aspirin  
• Compared to nonselective NSAIDs, COX-2 inhibitors may reduce—but do not eliminate—risk of gastrointestinal bleeding  
• Prolonged use of indomethacin, piroxicam, tolmetin, and meclofenamate should be avoided because of central nervous system side effects |
| Opioid analgesics (short- and long-acting varieties of codeine, hydrocodone, oxycodone, morphine, methadone, fentanyl) | **Indications**  
• Use of fentanyl is not recommended unless shorter-acting opioids have been tried unsuccessfully, or titration of shorter-acting doses has established a clear daily dose of opioid analgesic that can be provided by using an extended-release form, while also minimizing complications |
|                            | **Adverse Consequences**                                                                                                                                                                                                 |
|                            | • High incidence of significant adverse consequences including nausea, vomiting, anorexia, sedation, lethargy, weakness, confusion, agitation, dysphoria, depression, psychosis, hallucinations  
• May cause respiratory depression, especially in individuals with compromised pulmonary function |
| Pentazocine                 | **Indications**  
• Limited effectiveness because it is a partial agonist-antagonist  
• Not recommended for use in the elderly |
|                            | **Adverse Consequences**                                                                                                                                                                                                 |
|                            | • This opioid analgesic causes more central nervous system side effects including confusion and hallucinations more commonly than other }
## Medication Issues and Concerns

<table>
<thead>
<tr>
<th>Medication</th>
<th><strong>Issues and Concerns</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>opioid analgesics</strong></td>
<td>- Additional side effects include dizziness, lightheadedness, euphoria, sedation, hypotension, tachycardia, syncope</td>
</tr>
</tbody>
</table>
| **Prooxyphene (Darvon)** and combination products (Darvon with ASA, Darvon-N and Darvocet-N) | **Indications**  
  - Offers few analgesic advantages over acetaminophen, yet has the adverse effects, including addiction risk, of other opioid medications  
**Adverse Consequences**  
  - Frequently associated with central nervous system effects (e.g., confusion drowsiness, dizziness) that can lead to other adverse consequences such as falls |
| **Antibiotics**                                                           | **Adverse Consequences**  
  - Any antibiotics can result in colitis, diarrhea, nausea, vomiting, anorexia, and hypersensitivity/allergic reactions; also vaginitis/vaginal infection (in women)  
  - Antibiotic-related diarrhea is not necessarily caused by clostridium difficile or associated with a positive clostridium difficile toxin assay |
| **Vancomycin/Gentamycin/Tobramycin**                                      | **Monitoring**  
  - Peak and trough blood levels and renal function tests should be done while the medication is being given  
  - Individual should be monitored for signs of toxicity, including hearing loss  
**Adverse Consequences**  
  - May cause or worsen ototoxicity, renal failure |
| **Anticoagulants**                                                        | **Monitoring**  
  - Use must be monitored periodically by Prothrombin Time (PT)/International Normalization Ratio (INR), with frequency determined by clinical circumstances, duration of use, and stability of monitoring results  
**Adverse Consequences**  
  - May interact with many other medications, which may affect serum concentrations of other medications or elevate the PT/INR, sometimes to levels potentially associated with life-threatening bleeding |
### Medication

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticonvulsants</strong></td>
<td></td>
</tr>
<tr>
<td>All anticonvulsants</td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Including phenytoin, phenobarbital, primidone, valproic acid, lamotrigine, levetiracetam, gabapentin, carbamazepine, oxcarbazepine</td>
<td>• Use of anticonvulsant medications should be related to documented evidence of a seizure disorder, or in individuals with a possible seizure; also may be used to treat bipolar disorder or chronic neuropathic pain, and for prophylaxis of migraine headaches</td>
</tr>
<tr>
<td></td>
<td>• Need for indefinite continuation should be based on confirmation of the condition (for example, distinguish epilepsy from isolated seizure due to medical cause) and its potential causes (medications, electrolyte imbalance, hypocalcemia, etc.).</td>
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<tr>
<td></td>
<td><strong>Monitoring</strong></td>
</tr>
<tr>
<td></td>
<td>• Serum concentrations may help identify toxicity, but significant signs and symptoms can occur even at normal or low serum concentrations</td>
</tr>
<tr>
<td></td>
<td>• When anticonvulsants are used as a mood stabilizer, the same concerns exist regarding the need for monitoring for effectiveness and side effects; but evaluation of symptoms—not serum concentrations—should be used to adjust doses. High or toxic serum concentrations should, however, be evaluated and considered for dosage adjustments.</td>
</tr>
<tr>
<td></td>
<td>• Symptom control for seizures or behavior can occur with low serum medication concentrations</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse Consequences</strong></td>
</tr>
<tr>
<td></td>
<td>• Anticonvulsants may cause liver dysfunction, blood dyscrasias, and serious skin rashes requiring discontinuation of treatment</td>
</tr>
<tr>
<td></td>
<td>• High incidence of nausea/vomiting, dizziness, ataxia, somnolence/lethargy, incoordination, blurred or double vision; may cause agitation, depression, psychosis, mania, toxic encephalopathy</td>
</tr>
<tr>
<td><strong>Antidepressants</strong></td>
<td></td>
</tr>
<tr>
<td>All antidepressants</td>
<td><strong>Dosage / Duration</strong></td>
</tr>
<tr>
<td></td>
<td>• Use of two or more antidepressants simultaneously may increase risk of side effects; in such cases, there should be documentation of expected benefits that outweigh the associated risks and monitoring for any increase in side effects.</td>
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<tr>
<td></td>
<td>• Duration should be in accordance with pertinent literature, including clinical practice guidelines; attempted tapering is warranted in some situations (for example, first episode of uncomplicated depression)</td>
</tr>
<tr>
<td>MAO inhibitors</td>
<td><strong>Indications/Contraindications</strong></td>
</tr>
</tbody>
</table>
### Medication | Issues and Concerns
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**Selective serotonin reuptake inhibitors (SSRIs)**
- Should not be administered to anyone with a confirmed or suspected cerebrovascular defect or to anyone with cardiovascular disease or hypertension
- Should not be used in the presence of pheochromocytoma

**Interactions**
- Should not be administered together or in rapid succession with other MAO inhibitors, tricyclic antidepressants, bupropion, SSRIs, buspirone, sympathomimetics, meperidine, triptans, and other medications that affect serotonin or norepinephrine, cheese or other foods with a high tyramine content

**Adverse Consequences**
- May cause dizziness, nausea, diarrhea, anxiety, nervousness, insomnia, somnolence, weight gain, anorexia, or increased appetite
- May increase suicide risk in susceptible individuals

**Tricyclic antidepressants (TCAs) (amitriptyline, doxepin, etc.; including combination products such as amitriptyline and chlordiazepoxide (Limbitrol), amitriptyline and perphenazine (Triavil)**

**Indications**
- Because of strong anticholinergic and sedating properties, TCAs and combination products are rarely the medication of choice for the elderly

**Exception:** Use of TCAs may be appropriate if:
  - The resident is being treated for neurogenic pain (i.e., trigeminal neuralgia, peripheral neuropathy), based on documented evidence to support the diagnosis; and
  - The relative risks/benefits—including alternative pain therapies that may have fewer side effects in the individual—have been considered.

**Adverse Consequences**
- Compared to other categories of antidepressants, tricyclic antidepressants (TCAs) cause significant anticholinergic side effects and sedation

**Anti-diabetic medications**

**Insulin and oral hypoglycemics**

**Monitoring**
- Use of anti-diabetic medications should include monitoring (for example, regularly scheduled blood sugars) for effectiveness based on
Medication | Issues and Concerns
--- | ---
desired goals for that individual and to identify complications of treatment such as hypoglycemia, impaired renal function, or lactic acidosis (for example, with metformin use)

**NOTE:** It may not be possible to control blood sugars initially, or they may fluctuate, or it may be deemed undesirable to tightly control blood sugar, but efforts to stabilize blood sugar levels are important. Long-term sliding scale insulin for non-emergency coverage may not be a true indicator of blood sugar control.

**Chlorpropamide (Diabinese)**
**Glyburide (Micronase)**

**Adverse Consequences**
- Prolonged half-life or duration of action in older individuals can cause prolonged and serious hypoglycemia (including tachycardia, palpitations, irritability, headache, hypothermia, visual disturbances, lethargy, confusion, seizures and/or coma)
- Chlorpropamide and other sulfonylureas can cause the syndrome of inappropriate antidiuretic hormone (SIADH) and result in hyponatremia

**Trimethobenzamide (Tigan)**

**Adverse Consequences**
- Relatively ineffective antiemetic that can cause significant extrapyramidal side effects in addition to lethargy, sedation, confusion

*Exception:* May be indicated in patients with Parkinson’s Disease taking apomorphine (Apokyn)

**Anti-infectives**

**Nitrofurantoin (Macrodantin)**

**Indications / Adverse Consequences**
- Because of decreased effectiveness in residents with a CrCl <60 ml/min and its side effects (e.g., acute, subacute, and chronic pulmonary reactions and peripheral neuropathy), it is not the anti-infective/antibiotic of choice for treatment of acute or prophylactic urinary tract infection
- Safer alternatives are available

**Fluconazole (anti-fungal)**

**Indications**
- Should be used in lowest possible dose for shortest possible duration, especially in anyone receiving other medications known to interact with fluconazole, based on documented appraisal of why the situation warrants treatment and why alternative, lower-risk approaches (for
### Medication Issues and Concerns

Example, topical antifungal) are not warranted, whether individual is receiving medications that can cause dangerous interactions, and evidence that benefits warrant the risks **Interactions**
- Interacts with many other medications
- Interaction with warfarin can cause markedly elevated PT/INR, increasing bleeding risk

#### Anti-manic medication

**Lithium**

**Indications**
- Should generally not be given to individuals with significant renal or cardiovascular disease, severe debilitation or dehydration, or sodium depletion

**Monitoring**
- Toxic levels are very close to therapeutic levels. Serum lithium concentration should be monitored periodically, and dosage adjusted accordingly

**Adverse Consequences**
- Potentially dangerous sodium imbalance may occur
- Adverse consequences may occur at relatively low serum concentrations (1-1.5 mEq/L)

#### Anti-Parkinson medications

Including levodopa, carbidopa/levodopa, selegiline, bromocriptine, entacapone, and various combinations

**Adverse Consequences**
- May cause significant agitation, confusion, restlessness, delirium, psychosis, nausea, vomiting, dizziness, hallucinations, constipation
- Increased risk of postural hypotension, especially when given in conjunction with antihypertensive medications

#### Antipsychotic medications

**Conventional Agents**

- Chlorpromazine (Thorazine)
- Fluphenazine (Prolixin)
- Haloperidol (Haldol)

**Indications**
- Prior to initiation of an antipsychotic, the staff should monitor behaviors objectively and qualitatively, in order to 1) identify preventable and correctable causes for distressed behavior such as environmental and psychosocial stressors, 2) demonstrate that the behavior is persistent, and 3) have a measurable way to determine the
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
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</thead>
<tbody>
<tr>
<td>Loxapine (Loxitane)</td>
<td>effectiveness of the antipsychotic, if warranted.</td>
</tr>
<tr>
<td>Mesoridazine (Serentil)</td>
<td>• An antipsychotic medication should be used only for one of the following indications, unless there is another clearly documented clinical justification:</td>
</tr>
<tr>
<td>Molindone (Moban)</td>
<td>1) Schizophrenia;</td>
</tr>
<tr>
<td>Perphenazine (Trilafon)</td>
<td>2) Schizo-affective disorder;</td>
</tr>
<tr>
<td>Promazine (Sparine)</td>
<td>3) Delusional disorder;</td>
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<tr>
<td>Thioridazine (Mellaril)</td>
<td>4) Psychotic mood disorders (including mania and depression with psychotic features);</td>
</tr>
<tr>
<td>Thiothixene (Navane)</td>
<td>5) Acute psychotic episodes;</td>
</tr>
<tr>
<td>Trifluoperazine (Stelazine)</td>
<td>6) Brief reactive psychosis;</td>
</tr>
<tr>
<td>Triflupromazine (Vesprin)</td>
<td>7) Schizophreniform disorder;</td>
</tr>
<tr>
<td>Aripiprazole (Abilify)</td>
<td>8) Atypical psychosis;</td>
</tr>
<tr>
<td>Clozapine (Clozaril)</td>
<td>9) Tourette’s disorder;</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa)</td>
<td>10) Huntington’s disease;</td>
</tr>
<tr>
<td>Quetiapine (Seroquel)</td>
<td>11) Organic mental syndromes (including dementia, amnestic and other cognitive disorders defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or subsequent editions) with associated psychotic behaviors or aggressive behaviors (e.g., uncontrolled or recurrent verbal or physical aggression destructiveness) that either:</td>
</tr>
<tr>
<td>Risperidone (Risperdal)</td>
<td>• present a danger to the resident or to others; or</td>
</tr>
<tr>
<td>Ziprasidone (Geodon)</td>
<td>• are significant enough to cause the resident to experience inconsolable distress (e.g., severe anxiety or fear, continuous yelling, screaming, or crying), or a significant decline in function (e.g., refusal to eat, pacing that impedes nutrition or fluid intake, fear and refusal to bathe for more than one week);</td>
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<td></td>
<td>AND:</td>
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<td></td>
<td>• are continuous or frequently recurrent;</td>
</tr>
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<td></td>
<td>• have specific, clearly identified target behaviors;</td>
</tr>
<tr>
<td></td>
<td>• do not result from environmental stressors (e.g., alteration in the resident’s customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise, ineffective staff response, physical barriers, etc.) that can be readily addressed to improve the symptoms or maintain safety;</td>
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<tr>
<td></td>
<td>• do not result from a medical condition or problem (e.g.,</td>
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<td>Medication</td>
<td>Issues and Concerns</td>
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<tr>
<td>pain, infection, headache, fluid/electrolyte imbalance, hypoxia, hearing or visual impairment, etc.) that can be addressed to improve the symptoms or maintain safety; and</td>
<td></td>
</tr>
<tr>
<td>• do not result from psychological stressors (e.g., losses, loneliness, taunting, abuse, insufficient individualized activities) that can be readily addressed to improve the symptoms or maintain safety; and</td>
<td></td>
</tr>
<tr>
<td>• nonpharmacologic interventions do not substantially reduce or relieve the symptoms or maintain safety.</td>
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</table>

Antipsychotics should not be used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) anxiety; 6) depression (without psychotic features); 7) insomnia; 8) unsociability; 9) inattention or indifference to surroundings; 10) fidgeting; 11) nervousness; 12) uncooperativeness; or 13) verbal expressions or behavior that does not represent a danger to the resident or others.

**Documentation**

- Documentation may take several forms; for example, dedicated forms or “behavior monitoring” tools, staff or practitioner progress notes, etc.
- Documentation should be both qualitative (for example, description of the target behavior) and quantitative (for example, frequency and duration of the behavior)
- Such documentation is needed to help:
  - Describe the target behavior in enough detail to permit further decisions about appropriate interventions (often referred to as “behavioral monitoring”);
  - Identify the characteristics and possible causes of an individual’s behavior;
  - Determine whether the behavior is sufficiently severe to warrant an intervention;
  - Determine whether the behavioral symptom is temporary or enduring;
  - Evaluate the effectiveness of the interventions employed.
- Although a specific monitoring tool is not required, examples of such tools that may be employed to document behavior may include (but are not limited to):
  - Cohen-Mansfield Agitation Inventory;
Medication | Issues and Concerns
--- | ---
 | o Behavioral Pathology in Alzheimer’s Disease Rating Scale (Behave AD);
 | o Hamilton Anxiety Scale (HAM-A); or
 | o facility-designed shift monitoring forms.

Refer to the RAPs for a more complete description of how behavioral monitoring can help with the differential diagnosis of behavioral symptoms.

**Dosage / Duration**
- Doses for acute indications (for example, acute psychosis) may differ from those used for long-term treatment, but should be the lowest possible to achieve the desired therapeutic effects
- Doses for long-term use should be the lowest possible to achieve the desired therapeutic goals, with attempted gradual dose reduction at least every 6 month period as discussed elsewhere in this guidance, unless contraindicated
- Effective dosages may differ for different age groups and diagnoses
- Any doses that exceed the low end of a manufacturer’s recommendations or other published guidance on dosage for a similar population should have documented clinically pertinent justification

**Monitoring**
- There must be evidence that antipsychotic medications are monitored for their effectiveness and for adverse consequences
- Examples of such monitoring (at baseline and as appropriate, periodically thereafter) may include weight, orthostatic blood pressure, behavior and function, liver function tests, fasting blood glucose, HbA1c, and documented assessment for parkinsonism, akathisia, tardive dyskinesia, falls, lethargy, and worsening confusion or cognition.

**Adverse consequences**
Each antipsychotic medication has a profile of potential adverse consequences of varying degrees of severity. Some of the more common adverse consequences include: 1) sedation; 2) extrapyramidal and psychomotor effects (e.g., lethargy, restlessness); 3) anticholinergic effects (see Table II); 4) orthostatic hypotension; 5) edema; 6) falls; 7) decreased sweating; 8) neuroleptic malignant syndrome (NMS); 9) increasing confusion or agitation; 10) affective symptoms (e.g., mania, depression); 11) tardive dyskinesia; 12) akathisia; 13) Parkinsonism; 14)
<table>
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<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
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</table>
| Atypical antipsychotic agents     | • Blood sugar elevation (including diabetes mellitus)  
• Cerebrovascular event (such as stroke, transient ischemic attack [TIA]) in elderly individuals with dementia  
• Death secondary to heart-related events (e.g., heart failure, sudden death) |
| Anxiolytics                       |                                                                                                                                                  |
| Benzodiazepines (Short-Acting)    | **Indications**  
• Short-acting benzodiazepines should not be used unless: 1) there is documented evidence that other possible causes of the resident’s distress have been considered and ruled out; 2) its use results in maintenance or improvement in the resident’s function (as reflected on the MDS); 3) daily use is for less than four continuous months, unless at least 3 attempts at a gradual dose reduction within a 6-month period are unsuccessful; 4) it is used in the lowest possible dose required to treat the resident’s condition, unless higher doses (as evidenced by the resident’s response and/or the resident’s clinical record) are necessary to maintain or improve the resident's function.  
• Short-acting benzodiazepines should only be used for one of the following indications, as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV): a) generalized anxiety disorder; b) panic disorder; c) symptomatic anxiety that occurs in someone with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); d) sleep disorders; e) acute alcohol or benzodiazepine withdrawal; or f) dementia, delirium, amnestic, and other cognitive disorders (as specified by the DSM-IV) with associated behaviors that: i) indicate clinically significant distress or dysfunction, or present a danger to the resident or others; ii) are quantitatively and objectively documented; iii) are persistent; and iv) are not due to other preventable or correctable reasons. |
| Benzodiazepines (Long-Acting)     | **Indications**  
• Long-acting benzodiazepines should not be used in older individuals unless an attempt with a shorter-acting medication (i.e., short-acting benzodiazepines or other anti-anxiety agents/sedatives, or medications used for sleep induction) has failed  
**Exception:** Use of some benzodiazepines in the following circumstances may be appropriate:  
  o long-acting benzodiazepines used to withdraw someone from...
### Medication Issues and Concerns

- short-acting benzodiazepines or alcohol;
  - diazepam used in neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia, or seizure disorders); or
  - clonazepam used in bipolar disorder, nocturnal myoclonus, or seizure disorders.

**Adverse Consequences**
- Long-acting benzodiazepines have a long half-life (up to several days) in older individuals. This means that they can accumulate and cause excessive sedation and increased incidence of falls and fractures

<table>
<thead>
<tr>
<th>Medication</th>
<th>Indications</th>
<th>Dosage / Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meprobamate (Miltown, Equanil)</td>
<td>Highly addictive and sedating anti-anxiety agent; not indicated for usage in elderly</td>
<td>Those who have used meprobamate for prolonged periods may be addicted and may need to be withdrawn slowly</td>
</tr>
</tbody>
</table>

### Cardiovascular medications (including antihypertensives)

**Adverse Consequences**
Cardiac antiarrhythmics can have serious adverse effects in older individuals, including impaired mental function, appetite, behavior, and heart function

<table>
<thead>
<tr>
<th>– Amiodarone</th>
<th>Indications</th>
<th>Dosage / Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Only approved indication for use is to treat documented life-threatening recurrent ventricular arrhythmias that do not respond to other antiarrhythmic agents or when alternative agents are not tolerated</td>
<td>It is critical to carefully consider risks and benefits, to use the lowest possible dose for the shortest possible duration, to closely monitor individuals receiving long-term amiodarone, and to seek and identify potential and actual adverse drug reactions</td>
</tr>
<tr>
<td></td>
<td>Common off-label use to treat atrial fibrillation; however, recent literature suggests that in many higher risk individuals alternative approaches to managing atrial fibrillation (rate control and anticoagulation) are equally effective and less toxic*</td>
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<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
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<tr>
<td><strong>Adverse Consequences</strong></td>
<td>May cause potentially fatal toxicities, including pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) and hepatic injury. May cause hypothyroidism, exacerbate existing arrhythmia, and worsen heart failure. Can also impair mental function and behavior</td>
<td></td>
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<tr>
<td></td>
<td>Toxicity increases with higher doses and longer duration of use</td>
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<tr>
<td><strong>Disopyramide (Norpace and Norpace CR)</strong></td>
<td>Adverse Consequences</td>
<td></td>
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<tr>
<td></td>
<td>Disopyramide (Norpace or Norpace CR) has potent negative inotropic effects (decreased force of heart contraction), may induce heart failure in older individuals, and is also strongly anticholinergic</td>
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</tr>
<tr>
<td><strong>Antihypertensives</strong></td>
<td>Adverse Consequences</td>
<td></td>
</tr>
<tr>
<td>– Angiotensin converting enzyme (ACE) inhibitors</td>
<td>May cause hyperkalemia or worsen renal failure</td>
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<td></td>
<td>May cause angioedema (signs and symptoms of immediate hypersensitivity)</td>
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<td></td>
<td>Should be used cautiously in combination with potassium supplements, potassium-sparing diuretics including spironolactone; benefits of combination use should be evaluated as outweighing risks; potassium should be monitored closely</td>
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<tr>
<td></td>
<td>Some ACE inhibitors may cause chronic persistent nonproductive cough</td>
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</tr>
<tr>
<td>– Angiotensin II receptor blockers</td>
<td>Adverse Consequences</td>
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<td></td>
<td>May cause bradycardia (excessively slow heart rate), especially in individuals receiving other medications that affect cardiac conduction</td>
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<tr>
<td></td>
<td>May cause excessive dizziness, fatigue; may exacerbate depression</td>
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<td></td>
<td>May cause or exacerbate bronchospasm (especially, but not exclusively, propranolol)</td>
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<tr>
<td></td>
<td>May need to adjust dose in acute heart failure; may exacerbate cardiac decompensation</td>
<td></td>
</tr>
<tr>
<td>– Beta adrenergic blockers Including nonselective (propranolol) and cardioselective (atenolol, esmolol, metoprolol, nadolol,</td>
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</table>
### Medication Issues and Concerns

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
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</thead>
</table>
| timolol | - Should be used cautiously in individuals at risk for hypoglycemia as they may mask tachycardia associated with symptomatic hypoglycemia  
- Should be used cautiously in individuals with hepatic impairment and those who are also receiving calcium channel blockers, reserpine, or MAO inhibitors |
| Calcium channel blockers  
Including nifedipine, isradipine, amlodipine, nisoldipine, diltiazem, verapamil | **Adverse consequences**  
- May cause clinically significant constipation  
- May cause peripheral edema  
- Higher doses may cause generalized aching, headache, muscle pain |
| Methyldopa (Aldomet)  
Including combination products such as Methyldopa hydrochlorothiazide (Aldoril) | **Indications**  
- Alternate treatments for hypertension are preferred  
**Adverse Consequences**  
- May cause bradycardia and excessive sedation; may exacerbate depression in the geriatric population |
| Digoxin | **Indications**  
- Digoxin should be used only for one of the following diagnoses: congestive heart failure, atrial fibrillation, paroxysmal supraventricular tachycardia, or atrial flutter  
- Should be used with caution in individuals with impaired renal function  
**Dosage**  
- Daily doses should ordinarily not exceed 0.125 mg/day except when used to control atrial arrhythmia and slow ventricular rate  
**Interactions**  
- May interact with many other medications, possibly resulting in digoxin toxicity or elevated serum concentrations of other medications  
**Monitoring**  
- Must be used cautiously in individual with renal failure or fluid and electrolyte imbalance, with close monitoring for adverse consequences and monitoring, as indicated, of both renal function |
<table>
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<th>Medication</th>
<th>Issues and Concerns</th>
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<tbody>
<tr>
<td>and serum medication concentration (“digoxin level”)</td>
<td></td>
</tr>
<tr>
<td>• Side effects may occur even with therapeutic serum concentration, especially in the geriatric population</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>• May cause significant bradycardia especially when used in individuals taking other medications affecting cardiac conduction</td>
<td></td>
</tr>
<tr>
<td>• Toxicity may cause nausea, vomiting, anorexia, delirium, cardiac arrhythmia</td>
<td></td>
</tr>
<tr>
<td><strong>Diuretics</strong></td>
<td></td>
</tr>
<tr>
<td>Including furosemide, hydrochlorothiazide, spironolactone, triamterene, bumetanide, metolazone, ethycrinic acid, torsemide</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>• May cause fluid and electrolyte imbalance (hyponatremia, hypokalemia, dehydration, etc.), hypotension; may precipitate or exacerbate urinary incontinence, falls</td>
<td></td>
</tr>
<tr>
<td>• Hyperkalemia may occur with triamterene, spironolactone, or when excess diuresis leads to intravascular volume depletion/prerenal azotemia</td>
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</tr>
<tr>
<td>• Hypernatremia may occur when excess diuresis leads to water loss in excess of sodium depletion</td>
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<tr>
<td><strong>Nitrates</strong></td>
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<tr>
<td>Including isosorbide mononitrate, isosorbide dinitrate, nitroglycerin</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td></td>
</tr>
<tr>
<td>• May cause dizziness, lightheadedness, faintness, or symptomatic orthostatic hypotension, especially if taken in combination with antihypertensive medications</td>
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<tr>
<td>• May cause headache</td>
<td></td>
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<tr>
<td><strong>Cholesterol lowering medications</strong></td>
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<tr>
<td>All statins</td>
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<tr>
<td><strong>Adverse Consequences</strong></td>
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</tr>
<tr>
<td>• May impair liver function; liver function tests should be done prior to initiation, at 12 weeks following initiation, and periodically (approximately every 6 months) thereafter</td>
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</tr>
<tr>
<td>• May cause muscle pain, myopathy, and rhabdomyolysis (breakdown of skeletal muscle) that can precipitate kidney failure</td>
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<tr>
<td><strong>Cholestryramine</strong></td>
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<tr>
<td><strong>Interactions</strong></td>
<td></td>
</tr>
<tr>
<td>• May interact with many other medications, including anticoagulants, digoxin, diuretics, thyroid hormone, and Vancomycin</td>
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</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td></td>
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<tr>
<td>• May cause constipation, dyspepsia, nausea or vomiting, abdominal</td>
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</table>
## Medication Issues and Concerns

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholinesterase inhibitors</td>
<td><strong>Indications</strong>&lt;br&gt;- Have specific, limited approved indications&lt;br&gt;- Effectiveness may change over time as underlying disorder progresses</td>
</tr>
<tr>
<td>Including donepezil (Aricept), galantamine (Reminyl), rivastigmine (Exelon)</td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;- May affect cardiac conduction, especially in individuals who already have cardiac conduction disorder or who are taking other medications that affect heart rate&lt;br&gt;- May cause insomnia, dizziness, nausea, vomiting, diarrhea, anorexia, and weight loss&lt;br&gt;- Should be used with caution in individuals with severe asthma or obstructive pulmonary disease</td>
</tr>
<tr>
<td>Cough, cold, and allergy medications</td>
<td><strong>Indications / Duration</strong>&lt;br&gt;- Should be used only for a limited duration (less than 7 days) unless documented evidence of enduring symptoms that cannot otherwise be alleviated and for which a correctable cause cannot be identified</td>
</tr>
<tr>
<td>All cough, cold, allergy medications</td>
<td><strong>Indications</strong>&lt;br&gt;- H-1 blocker antihistamines have strong anticholinergic properties and are not considered medications of choice for the management of anxiety or insomnia in the elderly&lt;br&gt;- If appropriate and effective, topical instead of oral diphenhydramine should be considered for allergic reactions involving the skin</td>
</tr>
<tr>
<td>Antihistamines H-1 blockers including:&lt;br&gt;Diphenhydramine (Benadryl), Cyproheptadine (Periactin), Promethazine (Phenergan), Hydroxyzine (Atarax, Vistaril), Chlorpheniramine (Chlortrimeton), Meclizine (Bonine, Antivert)</td>
<td><strong>Dosage / Duration</strong>&lt;br&gt;- When used to treat or prevent allergic reactions, antihistamines should be used in the smallest possible dosage for the shortest possible duration and with great caution, especially in individuals susceptible to anticholinergic side effects or who are receiving other medications with anticholinergic properties (see Table II)</td>
</tr>
<tr>
<td>Oral decongestants</td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;- May cause excessive sedation, confusion, cognitive impairment, agitation, dry mouth, constipation, urinary retention</td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
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<tr>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
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</tbody>
</table>
| (Including, but not limited to, pseudoephedrine)                          | • May cause dizziness, nervousness, insomnia, palpitations, urinary retention, elevated blood pressure  
  • Should be used with caution in individuals who have insomnia or hypertension |
| Gastrointestinal medications                                             | **Adverse Consequences**                                                              |
| Gastrointestinal (GI) antispasmodics                                      | • Highly anticholinergic effects; generally produces substantial toxic effects in older individuals (see Table II). Effectiveness at doses tolerated by the elderly is questionable.  
  • All of these medications are best avoided in the older individuals, especially for long-term use.  
  **Exception:** Use of GI antispasmodic medications may be appropriate if occasional (once every three months) for a short period (not more than seven days) for symptoms of an acute, self-limited condition for which a correctable cause cannot be readily identified. |
| Including dicyclomine (Bentyl), hyoscyamine (Levsin, Levsinex, Propantheline), Belladonna alkaloids (Donnatal and others), Clidinium and chlordiazepoxide (Librax) | **Indications**                                                                      |
| Metoclopramide (Reglan)                                                  | • High-risk medication with very limited demonstrated effectiveness *  
  • Not recommended for first-line treatment of gastroesophageal reflux disease, especially in the elderly and other susceptible individuals  
  **Adverse Consequences**                                                              |
|                                                                             | • Especially in the elderly and other susceptible individuals, metoclopramide may cause restlessness, drowsiness, insomnia, depression, agitation, anorexia, and extrapyramidal symptoms, and may lower the seizure threshold.  
  • Should be used with caution in patients with seizure disorders or Parkinson’s Disease |
| Proton pump inhibitors (PPI)                                               | **Indications**                                                                      |
| Including omeprazole, esomeprazole, rabeprazole, lansoprazole             | • Indications for long-term use of medications in this category are specific and limited  
  • When used to treat suspected GERD, the diagnosis should be based on clinical symptoms and/or endoscopic findings, not solely on the fact that the individual is taking a medication in this category |
### Medication Issues and Concerns

<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td>- When used for the treatment or prevention of NSAID-induced gastritis, documentation should exist that other, less GI-toxic analgesics have been tried or were not indicated</td>
</tr>
<tr>
<td><strong>Adverse Consequences</strong></td>
<td>- May cause or exacerbate headache, nausea, vomiting, flatulence, dysphagia, abdominal pain, diarrhea, other gastrointestinal symptoms; persistence or recurrence of such symptoms while taking PPI should lead to consideration of whether continued use of the medication is indicated</td>
</tr>
<tr>
<td><strong>Glucocorticoids</strong></td>
<td>- Intermediate- or longer-term use may cause hyperglycemia, psychosis, edema, insomnia, hypertension, osteoporosis</td>
</tr>
<tr>
<td>Including non-topical, non-inhaled dosage forms of hydrocortisone, methylprednisolone, dexamethasone, prednisone</td>
<td><strong>Duration / Monitoring</strong></td>
</tr>
</tbody>
</table>

<p>| <strong>Hematinics</strong> | <strong>Indications</strong> | - Indications are limited and specific  |
| <strong>Erythropoiesis stimulants</strong> | <strong>Monitoring</strong> | - Use must be monitored according to specific manufacturer’s instructions including periodic CBC to permit tapering or discontinuation when hemoglobin exceeds target ranges  |
| Including erythropoietin, darbepoietin | <strong>Adverse Consequences</strong> | - Should not be given to individuals with poorly controlled hypertension  |
| | | - Excessive dose or duration can lead to polycythemia, dangerous thrombotic events including myocardial infarction and stroke  |
| <strong>Iron</strong> | <strong>Indications</strong> | - Iron therapy is not indicated in anemia of chronic disease when iron stores and transferrin levels are normal or elevated  |
| | <strong>Adverse Consequences</strong> | - May cause constipation, dyspepsia  |
| | | - Can accumulate in tissues and cause multiple complications if given chronically despite normal or high iron stores  |</p>
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laxatives</strong>&lt;br&gt;All categories including bulk producing laxatives, hyperosmolar agents, saline laxatives, stimulant laxatives, emollient laxatives</td>
<td><strong>Adverse Consequences</strong>&lt;br&gt;• May cause flatulence, bloating, abdominal pain&lt;br&gt;• Laxatives and stool softeners must be used with adequate fluids to avoid accumulation and possible obstructive symptoms</td>
</tr>
<tr>
<td><strong>Muscle relaxants</strong>&lt;br&gt;All muscle relaxants including methocarbamol (Robaxin), carisoprodol (Soma), chlorzoxazone (Paraflex), metaxalone (Skelaxin), cyclobenzaprine (Flexeril), dantrolene (Dantrium), orphenadrine (Norflex, Banflex, Myotrol), lioresal (Baclofen)</td>
<td><strong>Indications / Adverse Consequences</strong>&lt;br&gt;• Mostly poorly tolerated by older individuals, due to anticholinergic side effects (see Table II), sedation, or weakness&lt;br&gt;<strong>Exception:</strong> Periodic use (once every three months) for a short duration (not more than seven days) may be appropriate, where other interventions or alternative medications are not effective or not indicated.&lt;br&gt;• Abrupt cessation of some muscle relaxants may cause or predispose to seizures or hallucinations</td>
</tr>
<tr>
<td><strong>Orexigenics (appetite stimulants)</strong>&lt;br&gt;Megesterol acetate&lt;br&gt;Oxandrolone (Oxandrin)&lt;br&gt;Dronabinol (Marinol)</td>
<td><strong>Indications</strong>&lt;br&gt;• Use should be reserved for situations where assessment and management of underlying correctable causes of anorexia and weight loss is not feasible or not successful, and after evaluating potential benefits/risks&lt;br&gt;<strong>Duration</strong>&lt;br&gt;• Duration should be for a limited time, not indefinitely&lt;br&gt;<strong>Adverse Consequences</strong>&lt;br&gt;• Megesterol acetate may cause fluid retention, adrenal suppression, symptoms of adrenal insufficiency&lt;br&gt;• Oxandrin may cause virilization of females and feminization of males, excessive sexual stimulation, fluid retention&lt;br&gt;• Marinol may cause tachycardia, orthostatic hypotension, dizziness, dysphoria, and impaired cognition</td>
</tr>
<tr>
<td><strong>Osteoporosis medications</strong></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Issues and Concerns</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>
| Bisphosphonates Including risedronate (Actonel), alendronate (Fosamax), ibandronate (Boniva) | **Dosage**  
• These medications must be taken according to very specific directions, including time of day, position, time in relation to other medications and food  
**Monitoring**  
• Individuals receiving these medications should be monitored closely for gastrointestinal complications  
**Adverse Consequences**  
• Potential to cause gastrointestinal symptoms including dysphagia, esophagitis, gastritis, or esophageal and gastric ulcers, especially when given to individuals who are also taking oral corticosteroids, aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) |
| Platelet inhibitors |  |
| Salicylates Including aspirin and other salicylates | **Adverse Consequences**  
• May cause gastrointestinal (GI) bleeding  
• Commonly associated with allergic reactions |
| Ticlopidine | **Adverse Consequences**  
• Associated with more severe side effects than other platelet inhibitors; considerably more toxic and should be avoided in the elderly.  
• Most serious side effects involve the hematologic system, including potentially life-threatening neutropenia.  
• May also cause nausea, vomiting, and diarrhea  
**Exception:** Use may be appropriate in individuals who have had a previous stroke or have evidence of stroke precursors (i.e., transient ischemic attacks (TIAs)), and who cannot tolerate aspirin or another platelet inhibitor |
| Clopidogrel | **Adverse Consequences**  
• Use cautiously with warfarin or NSAIDs because of increased risk of bleeding  
• May cause thrombocytopenia, increased risk of bleeding |
| Respiratory medications |  |
| Theophylline | **Interactions**  
• Potentially significant interactions with many other medications; |
Medication: Issues and Concerns

especially various antibiotics, seizure medications, and cardiac medications

**Monitoring / Adverse Consequences**

- There should be routine monitoring for signs and symptoms of toxicity, such as arrhythmia, seizure, GI upset, diarrhea, nausea/vomiting, abdominal pain, nervousness, headache, insomnia, agitation, dizziness, muscle cramp, tremor
- Periodic monitoring of serum concentrations may be useful to identify or verify toxicity

<table>
<thead>
<tr>
<th>Medication</th>
<th>Indications</th>
</tr>
</thead>
</table>
| All sedatives/hypnotics | Should only be used as part of a treatment plan to determine, where possible, the underlying cause of insomnia or the inability to initiate or maintain sleep (e.g., depression, pain, excessive noise or light, stimulating medications, caffeine, changes in lifelong routine), and other interventions (e.g., sleep hygiene interventions such as eliminating caffeine, noise, or light; establishing a regular bedtime routine, maximizing daily activity, calming the environment) have been attempted and evaluated (in some cases a sleep aid may be necessary for up to several weeks until the underlying aggravating factor can be identified and/or effectively treated, e.g., for sleep disturbance associated with depression until the antidepressant begins to work); and
| | o The use of a medication to induce sleep results in the maintenance or improvement of the resident’s function; and
| | o The dose of the medication is shown to be the lowest effective dose (as evidenced by the resident’s response and/or the resident’s clinical record) necessary to maintain or improve the resident’s function; and
| | o The medication is used daily for less than 14 continuous days, unless attempts at dose reduction have failed, or dose reduction is clinically contraindicated; and
| | o The medication is used in accordance with manufacturer’s recommendations; for example, duration and number of hours remaining in bed before arising as recommended on the label instructions.

**Exception:** Use of a single dose sedative for dental or medical procedures without additional justification is acceptable.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage / Duration</strong></td>
<td>Before concluding that a gradual dose reduction is clinically contraindicated, three consecutive attempts at dose reduction within a 6-month period must fail.</td>
</tr>
<tr>
<td></td>
<td>For individuals admitted to the facility who have been on nightly medications for sleep in the community, staff should attempt to withdraw these medications in accordance with gradual dose reduction requirements; however, depending on how long the resident has been taking them, it may take longer than 6 months to discontinue the medications. Surveyors should determine if the facility has a process in place to address residents admitted on nightly sleep medications.</td>
</tr>
<tr>
<td><strong>Barbiturates</strong></td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td></td>
<td>Barbiturates should not be initiated in any dose for any individuals; they are highly addictive and cause more adverse effects than most sedative or hypnotic medications in geriatric individuals</td>
</tr>
<tr>
<td></td>
<td><strong>Duration</strong></td>
</tr>
<tr>
<td></td>
<td>Residents currently using these medications or residents admitted to the facility while using these medications should receive gradual dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed.</td>
</tr>
<tr>
<td></td>
<td>A gradual dose reduction should be attempted at least twice within one year before concluding that the gradual dose reduction is clinically contraindicated.</td>
</tr>
<tr>
<td></td>
<td>Newly admitted residents using these medications may have a period of adjustment before a gradual dose reduction is attempted.</td>
</tr>
<tr>
<td></td>
<td>One exception to gradual dose reduction is when phenobarbital is used to treat seizure disorders.</td>
</tr>
<tr>
<td></td>
<td>These medications should not be withdrawn rapidly, as this might result in severe physiological withdrawal symptoms.</td>
</tr>
<tr>
<td><strong>Thyroid medications</strong></td>
<td><strong>Interactions</strong></td>
</tr>
<tr>
<td></td>
<td>Many clinically significant medication interactions have been identified.</td>
</tr>
<tr>
<td></td>
<td><strong>Dosage</strong></td>
</tr>
<tr>
<td></td>
<td>Initiation of thyroid supplementation should occur at very low doses and be increased gradually to avoid precipitating cardiac failure or</td>
</tr>
</tbody>
</table>
Medication Issues and Concerns

adrenal crisis

Monitoring

- Assessment of thyroid function (e.g., TSH, serum T4 or T3) should occur prior to initiation and periodically thereafter

**TABLE II**  
MEDICATIONS WITH SIGNIFICANT ANTICHOLINERGIC PROPERTIES

This table is provided because: 1) anticholinergic side effects are particularly common and problematic, especially in the elderly; 2) medications in many categories have anticholinergic properties; and 3) the use of multiple medications with such properties may be particularly problematic. The table lists common medications and adverse consequences, but is not all-inclusive.

<table>
<thead>
<tr>
<th>Class of Medication</th>
<th>Examples</th>
<th>Adverse consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihistamines (H-1 blockers)</td>
<td>Diphenhydramine (Benadryl) Cyproheptadine (Periactin) Promethazine (Phenergan) Hydroxyzine (Atarax,Vistaril) Chlorpheniramine (Chlortrimeton) Meclizine (Bonine, Antivert)</td>
<td><em>(Any of the following symptoms may be caused by any of the medications in the other columns, alone or in combination)</em></td>
</tr>
<tr>
<td>Respiratory Medications</td>
<td>Ipratropium (Atrovent) Tiotropium (Spiriva)</td>
<td><strong>Common</strong>  Slowed passage of food through digestive system Constipation Decreased sweating Dry mouth, nose skin etc. Elevated BP</td>
</tr>
<tr>
<td>GI antispasmodics</td>
<td>Dicyclomine (Bentyl) Hyoscynamine (Levsin.Levsinex) Propantheline (Probanthine) Belladonna (Donnatal) Clidinium/Chlordiazapoxide (Librax)</td>
<td><strong>Less Common</strong>  Bloat feeling Blurred vision Cognitive Decline (memory loss) Difficult urination or urinary retention Difficult swallowing (dry mouth) Drowsiness Headache Impaired attention Increases sensitivity of eyes to light</td>
</tr>
</tbody>
</table>
## Class of Medication

### SSRI
- Amoxapine (Ascendin)
- Cloimpramine (Anfranil)
- Imipramine (Tofranil)
- Protriptyline (Vivactil)
- Desipramine (Norpramine)
- Nortriptyline (Aventyl, Pamolor)

### Muscle relaxants
- Trazodone (Desyrel)
- Methocarbamol (Robaxin)
- Carisoprodol (Soma)
- Chlorzoxazone (Paraflex)
- Metaxalone (Skelaxin)
- Cyclobenzaprine (Flexeril)
- Dantrolene (Dantrium)
- Orphenadrine (Norflex, Banflex, Myotrol)

### Urinary Incontinence medications
- Oxybutynin (Ditropan)
- Probantheline (Probanthine)
- Tolterodine (Detrol, Detrol LA)
- Solifenacin (Vesicare)
- Darifenacin (Enablex)
- Trospium (Sanctura)

### Antiparkinson medications
- Benztropine (Cogentin)
- Trihexyphenidyl (Artane)
- Procyclidine (Kemadrin)
- Biperiden (Akineton)

### Antipsychotic medications
- See list of conventional antipsychotics in Table I above

## Adverse consequences
- Nausea or vomiting
- Unusual tiredness or weakness

**Serious signs of accumulation**
- Delirium
- Changes in vision/pain in eye
- Worsening glaucoma
- Clumsiness or unsteadiness
- Confusion / disorientation
- Convulsions
- Difficulty in breathing
- Dizziness
- Fast heart rate
- Fever
- Hallucinations
- Severe muscle weakness
- Severe fatigue
- Slurred speech
- Unusual excitement, nervousness
- Restlessness or irritability.
- Unusual warmth, dryness and flushing of skin.
- Paralytic ileus
INVESTIGATIVE PROTOCOL

UNNECESSARY MEDICATIONS and MEDICATION REGIMEN REVIEW

Objectives

• To determine whether the facility provides only those medications in the dose and for the duration that are necessary for each resident, according to his or her assessed needs;
  o Including whether alternative approaches had been considered, implemented and evaluated in an effort to reduce the need for or dose of a medication, as appropriate;

• To determine if the facility identifies the clinical rationale for use and parameters for monitoring of those medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences to the individual resident;

• To determine if the facility monitors the resident for the effectiveness of medications (including a comparison with therapeutic goals) as well as potential adverse consequences of those medications;

• To determine if gradual dose reductions were attempted for antipsychotics (unless clinically contraindicated) and tapering of other medications was considered, when indicated, in an effort to discontinue the use or reduce the dose of the medication;

• To determine if the facility’s staff recognize the onset or worsening of signs or symptoms, or a change in condition, and whether there was an evaluation to determine whether these may be related to the medication regimen, such as adverse drug reactions due to the initiation, duration, dose, etc. of a medication or combination of medications;

• To determine if the consultant pharmacist performed the monthly medication regimen review, and identified and reported pertinent issues related to the medication regimen including indications for use, dose, duration, and the potential for, or the likely existence of adverse consequences or other irregularities; and

• To determine whether and how the attending physician and director of nursing acted upon the report of irregularities.

Use
Use this protocol to evaluate the management of the medication regimen and the medication regimen review.

NOTE: This review is not intended to direct medication therapy. However, the surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that facility’s staff provide the necessary information to the physician for his/her review prior to responding to the surveyor’s inquiries.

Procedures

Request a copy and briefly review the medications currently ordered (prescription medications, over-the-counter medications, and herbal products) and/or discontinued by the practitioner, at least back to the most recent recapitulation/re-order of all medications.

If the resident is receiving a medication or medication combination that pose a risk of adverse consequences, determine whether the comprehensive care plan identified these medications and staff had established and implemented therapeutic goals and monitoring plans.

1. Observation

Use this brief review to focus your observations of the resident. To the extent possible, compare your observations with the therapeutic goals identified in the care plan and observe the resident’s physical, functional, and psychosocial status.

Use these baseline observations to direct additional record review, additional observations, and staff interviews regarding issues related to the use of medications and the potential impact on the resident. Use the table below to guide this additional review, including

- A review of all medications to identify indications for use, duration, dose (including duplicative therapy), and monitoring; and
- A review of the potential for or presence of adverse consequences that may be related to the medication(s).
SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS

Determine if the resident has experienced any of the following signs and symptoms:

- Dehydration / fluid and electrolyte imbalance
- Depression / mood disturbance
- Clinically significant constipation; bowel ileus, impaction
- Dysphagia / swallowing difficulty
- Urinary retention or incontinence
- Recurrent falls, dizziness, orthostatic hypotension
- Seizure activity
- Excessive sedation or lethargy
- New or worsening confusion or unusual behavior patterns
- Headaches, muscle pain, generalized aching or pain
- Rash, pruritus
- Anorexia, nausea, vomiting, unplanned weight loss
- Sleep disturbance
- Spontaneous or unexplained bleeding, bruising

REVIEW OF MEDICATIONS

Conduct a review of those medications and medication combinations that have a risk for adverse consequences, such as: cardiac, cholesterol-lowering, anti-diabetic; anticoagulants, anticholinergic; antihypertensive, diuretics, psychotherapeutic (including antipsychotic); anticonvulsants; antiparkinsons, antibiotics. See Tables I and II for examples.

NOTE: Do not include medications in which the risk for harm is minimal, such as vitamins.

Review for the presence or absence of the following components:

- Clinical indication for use of the medication;
- Behavioral interventions with antipsychotic medications;
- Excessive dose, including duplicative therapy;
- Duration;
- Monitoring;
- Adverse consequences; and
- Gradual dose reduction (for antipsychotic medications unless clinically contraindicated).

If observations or record review indicate symptoms or changes in condition (including transfers to acute care, since the last survey) that may be related to medications, note whether there was an:

- Initiation of new medication(s);
- Change in dose; or
- Whether there was an evaluation of the medication regimen as a potential root cause of the change.
2. Interview

Interview the resident and or family/responsible party, to the extent possible, to determine:

- His/her participation in care planning, including discussions of the therapeutic goals related to the use of medications; and
- His/her evaluation of the effectiveness of the medication therapy, such as decreasing symptoms of pain.

If condition changes or functional decline were identified that may be related to the medication regimen, interview knowledgeable staff to determine:

- Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
- Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen; and
- Whether the consultant pharmacist sought and identified signs and symptoms, or the staff informed the consultant pharmacist of them if they occurred after the last consultant pharmacist visit.

3. Consultant Pharmacist Review

Review the MRR to determine:

- If the consultant pharmacist had identified and reported existing medications with the potential for clinically significant adverse consequences to the attending physician and director of nursing; and
- Whether the attending physician and the director of nursing took action on the irregularities identified in the report. The responses from the attending physician could include the following:
  - The medication regimen was changed in response to the concern raised in the report (or after additional review of the situation);
  - A clinically pertinent rationale that is relevant to that specific resident’s signs and symptoms, prognosis, test results, etc. documents why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;
○ A clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or

○ The rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, a resident has recurrent seizures unless the dose is such that blood levels exceed the usual recommended therapeutic levels, and the attending physician and the facility are actively monitoring for, and addressing, adverse consequences).

• If the consultant pharmacist identifies a potential adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician. If the staff and consultant pharmacist identify a medication that they believe may be causing a serious adverse consequence or a clinically significant risk of adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, verify that the staff contacted the medical director to address the issue with the attending physician. If the attending physician is the medical director, determine if the facility has implemented a procedure for resolving concerns in this type of circumstance.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

After completing the Investigative Protocol, analyze the data in order to determine whether non-compliance with 42 CFR 483.25(l) exists.

Synopsis of Regulation (F329)

The unnecessary medication requirement has six aspects in order to assure that medication therapy is necessary and appropriate for the individual resident. The facility must assure that medication therapy (including antipsychotic agents) is based upon:

• An adequate indication for use;

• Use of the appropriate dose (reducing or discontinuing the dose if appropriate for the condition being treated);

• Behavioral interventions and gradual dose reduction (unless contraindicated) are provided for individuals receiving antipsychotics in an effort to reduce or discontinue the medication;

• Use for the appropriate duration;

• Adequate monitoring for efficacy and to detect the emergence or presence of adverse consequences;
• Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.

Criteria for Compliance

Compliance with 42 CFR 483.25(l), F329, Unnecessary medications

For a resident who has been or is receiving medication(s), the facility is in compliance if they:

• Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including the recognition and evaluation that the condition or symptoms may have reflected an adverse medication consequence;

• Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;

• Utilized those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident’s assessed condition(s);

• Considered tapering or dose reduction of other medications, where clinically applicable, in an effort to use the lowest effective dose possible or discontinue the medication as appropriate;

• Monitored the resident on an ongoing basis for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by resident condition and the nature of the medication;

• Reduced or discontinued the dose of a medication in response to adverse consequences, unless contraindicated; and

• Based on a comprehensive assessment, implemented a gradual dose reduction for each resident receiving long-term antipsychotic medications, unless clinically contraindicated; and utilized non-pharmacologic approaches to address the condition/symptoms prior to, or in conjunction with, medication therapy;

If not, cite F329.

Non-compliance for F329

After completing the investigation, determine whether or not compliance with the regulation exists. Non-compliance for F329 may include:
Inadequate Indications for Use – Examples of non-compliance related to medication being used without adequate indications include, but are not limited to:

- Failure to provide a documented clinical reason or demonstrate a clinically pertinent rationale for using medication(s) in a specific resident.
- Prescribing or administering a medication despite a known allergy to that medication.
- Failure to provide a clear clinical rationale for initiating or continuing a medication that ultimately resulted in an adverse consequence.
- Failure to consider underlying causes of symptoms that could be addressed by non-pharmacologic measures either prior to, or soon after, initiating a medication.
- Failure to consider and evaluate current medications as the underlying cause of a new or worsening symptom or complaint before adding another medication to treat that symptom or complaint.
- Initiation of a medication to manage distressed behavior without considering a possible underlying environmental or psychosocial stressor either before or shortly after initiation.
- Initiation of an antipsychotic medication for a condition or distressed behavior resulting from a medical cause (e.g., UTI, congestive heart failure) without trying to address the underlying cause or stressor or indicating why it could not or should not be addressed.
- Initiation of a medication presenting clinically significant risks such as metoclopramide, disopyramide, amiodarone, or an atypical antipsychotic without considering risks/benefits or potentially safer medications.
- Initiation or continuation of medications (e.g., acetaminophen, gabapentin) that depend on renal clearance without considering the impact of impaired kidney function.
- Concomitant use of two or more medications in the same class without a clinically pertinent explanation (could also be duplicative dose).
- Digoxin dose greater than 0.125mg daily for residents over 60 for reasons other than controlling ventricular rate, without a clinically pertinent rationale.

Inadequate Monitoring – Examples of non-compliance related to inadequate monitoring include, but are not limited to:
• Failure to monitor the response/medication effects and to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., reduction or relief of pain, or normalization of thyroid function) or the emergence of an adverse consequence.

• Absence of a plan to monitor for potential clinically significant adverse consequences (e.g., symptoms associated with digoxin toxicity, muscle pain due to cholesterol lowering medication).

• Failure to monitor a medication consistent with the standard of practice or manufacturer’s guidelines (e.g. use of warfarin without monitoring; long-term use of amiodarone without monitoring cardiac, pulmonary, thyroid, and liver function).

• Failure to carry out the monitoring that was ordered, or inadequate monitoring, for side effects/adverse consequences of medications with the potential for clinically significant adverse consequences. For example, use of warfarin in conjunction with:
  o Inadequate or absent evaluation, including PT/INR during treatment;
  o Failure to recognize and monitor the increased risk when the resident is receiving other medications (for example, digoxin, amiodarone, antibiotics, fluconazole, etc.) that are known to interact with warfarin and increase the PT/INR; and/or
  o Failure to act when the PT/INR exceeds the target goal.

**Excessive Dose (including duplicate therapy)** – Examples of non-compliance related to excessive dose include, but are not limited to:

• Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer’s label, clinical practice guidelines, or standards of practice for a resident’s age and condition, without a documented clinical rationale.

• Failure to consider the continued necessity of the dose or the possibility of tapering a medication.

• Failure to document a clinical rationale for using multiple medications from the same class.

• Initiation of risperidone at greater than 1 mg daily for a resident with dementia in the absence of a contraindication for a lower dose.

**Excessive Duration** – Examples of non-compliance related to excessive duration
include, but are not limited to:

- Continuation of a medication despite lack of evidence of therapeutic effectiveness; for example, indefinite continuation of cough, cold, and allergy medications that were initiated to treat acute upper respiratory symptoms without attempts to taper doses or evaluate whether underlying causes have resolved.

- Continuation beyond the manufacturer’s recommended time frames, the stop date or duration indicated on the medication order, or facility-established stop order policies without documented clinical justification.

- Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit, for example:
  
  - Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.
  
  - Administration of proton pump inhibitor (PPI) (e.g., esomeprazole) or full dose histamine 2 receptor antagonist (H2RA) (e.g., cimetidine) for greater than 12 weeks without verification of diagnosis or assessment of continuing need at this dosage level.
  
  - Failure to promptly re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency.

Adverse Consequences – Examples of non-compliance related to adverse consequences include, but are not limited to:

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of a clinically significant risk or probable current adverse consequences.

- Failure to evaluate the medication regimen of a resident with an unplanned weight loss and decreased appetite who is receiving a medication known to cause anorexia (e.g., cholinesterase inhibitors, digoxin toxicity).

Initiation of an Antipsychotic Medication in the Absence of a Specific Condition Diagnosed and Documented in the Record – Examples of non-compliance related to initiation of an antipsychotic include, but are not limited to:
• Failure to provide a documented clinical reason or demonstrate a clinically pertinent rationale for using an antipsychotic medication(s) in a specific resident.

• Initiating an antipsychotic for behavioral symptoms such as repeated attempts by a resident with dementia to leave the building before having assessed the resident for underlying causes and stressors or without having tried non-pharmacological approaches.

Antipsychotic Medications without Behavioral Interventions and Gradual Dose Reduction, Unless Contraindicated – Examples of non-compliance related to the GDR requirement include but are not limited to:

• Failure to attempt a GDR without identifying and documenting a contraindication to the GDR.

• Failure to attempt to reduce or discontinue the antipsychotic medication within the past 6 months, unless clinical contraindications are documented.

• Failure to implement behavioral interventions to attempt to reduce or discontinue the medication and there is no contraindication.

• Giving an antipsychotic medication indefinitely or for a prolonged period without attempting a GDR or behavioral interventions despite no identified contraindication to a GDR.

Potential tags for additional investigation:

If non-compliance with 483.25(l) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether non-compliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when non-compliance has been identified include the following:

• 42 CFR 483.10(h)(11), F157, Notification of changes
  o Review whether the facility contacted the attending physician regarding a significant change in the resident’s condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.

• 42 CFR 483.20(b), F272, Comprehensive assessments
  o Review whether the facility initially and periodically conducted a comprehensive, accurate assessment of the resident’s medications.
• 42 CFR 483.20(k)(1),(2), F279, F280, Comprehensive care plans
  o Review whether the facility developed a comprehensive care plan that was
    a) based on the assessment of the resident’s conditions, risks, needs, and
    behaviors; b) consistent with the resident’s goals and considered the need
    to monitor for effectiveness and emergence or presence of adverse
    consequences; and c) consistent with current standards of practice and
    considered manufacturers’ guidelines for use of the medication; and d)
    revised as needed to address medication-related issues.

• 42 CFR 483.25, F309, Quality of care
  o Review whether the facility had identified, evaluated, and responded to
    symptoms or condition changes that have a high potential to be related to
    medication adverse consequences such as increasing lethargy or excessive
    sedation, changes in bowel function, new or worsening symptoms of pain,
    or sleep disturbance.

• 42 CFR 483.25(a)(1), F310, Decline in ADL
  o Review whether the facility had identified, evaluated and responded to a
    new or rapidly progressive decline in function, movement disorders,
    increased fatigue and activity intolerance, in relation to potential
    medication adverse consequences.

• 42 CFR 483.25(d), F315, Urinary incontinence
  o Review whether the facility had identified, evaluated and responded to a
    change in urinary function or continence status in relation to potential
    medication adverse consequences.

• 42 CFR 483.25(f), F319-320, Mental and Psychosocial functioning
  o Review whether the facility had identified, evaluated, and responded to a
    change in behavior and/or psychosocial changes, including depression or
    other mood disturbance, agitation, restlessness, increasing confusion, or
    delirium, in relation to potential medication adverse consequences.

• 42 CFR 483.25(i)(1), F325, Nutritional parameters
  o Review if the facility had identified, evaluated and responded to a change
    in nutritional parameters, anorexia or unplanned weight loss, dysphagia
    and/or swallowing disorders in relation to potential medication adverse
    consequences.
• 42 CFR 483.25(i)(2), F327, Hydration
  o Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.

• 42 CFR 483.40(a), F385, Physician supervision
  o Review if the attending physician supervised the resident’s medical treatment, including assessing the resident’s condition, identifying the need for medication, and ordering and providing ongoing review of the medication regimen to address the resident’s needs and identify and address adverse consequences related to medications.

• 42 CFR 483.40(b), F386, Physician visits
  o Review if the attending physician or designee reviewed the resident’s total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.

• 42 CFR 483.60 F425, Pharmacy services
  o Review whether the consultant pharmacist has provided consultation regarding all aspects of the pharmacy services, including the availability, of medications, storage, medication integrity, or administering.

• 42 CFR 483.60(c), F428, Medication regimen review
  o Review whether the consultant pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.

• 42 CFR 483.75(i), F501, Medical director
  o Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a lack of response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to develop and implement policies and procedures for the safe and effective use of medications in the care of residents.
V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that non-compliance with the regulation at F329 exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F329 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.**

   Non-compliance related to an actual or potential harm/negative outcome for F329 may include, but is not limited to:

   - Potential for life-threatening toxicity from excessive dose or lack of indication for use of digoxin.

   - Complications (such as cardiac arrest, nephrotoxicity, deafness, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.

   - Fractures or falls with injury resulting from the continuing use of medications to induce sleep (hypnotics/sedatives), antipsychotics, antidepressants, antihypertensives, etc. in the presence of predisposing adverse consequences such as persistent dizziness or recurrent falling.

2. **Degree of harm (actual or potential) related to the non-compliance:**

   Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

   - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

   - If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. **The immediacy of correction required:**

   Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident’s health or safety exists by evaluating the deficient
practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety

Immediate Jeopardy is a situation in which the facility’s non-compliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to cause/allow/result in serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of the facility’s non-compliance that may cause or contribute to negative outcomes include:

- Failure to assess or respond appropriately for a resident taking warfarin and an antibiotic who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.

- Failure to monitor PT/INR for a resident on anticoagulant therapy in accord with standards of practice or to recognize and respond to a life threatening adverse consequence related to anticoagulation.

- Failure to monitor the effectiveness and adverse effects of antipsychotic use such as failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS) resulting in the resident’s hospitalization and/or death.

- Failure to attempt a GDR where a GDR was not contraindicated resulting in the resident developing tardive dyskinesia (which is commonly associated with high dose and prolonged antipsychotic therapy) while receiving an antipsychotic agent for a prolonged period.

- Failure to recognize, assess, or respond to the existing medications in the resident’s regimen (such as NSAIDs or COX-2 inhibitors, prednisone, bisphosphonates) as a potential cause of gastrointestinal bleeding, leading to hospitalization.
NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at severity level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates non-compliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident’s ability to maintain and/or reach his/her highest practicable well-being. Examples of non-compliance resulting in negative outcomes may include, but are not limited to:

- Facility failure to take appropriate action (e.g., holding the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising absent any trauma or frank bleeding occurs and the resident requires treatment (e.g., transfusion) and potentially hospitalization.

- Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anti-convulsants to treat recent-onset seizures that can be side effects or adverse consequences of medications such as: tramadol, theophylline, metoclopramide, propoxyphene in high doses, clozapine.

- Facility failure to implement a GDR for which there was no contraindication in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired gait.

NOTE: If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy

Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident’s ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided. Examples of deficient practices associated with actual or potential negative outcomes may include, but are not limited to:

- Facility failure to take appropriate action (e.g., change the warfarin dose) for a resident who has an INR greater than 3.5 and less than 9 without any bleeding.

- Failure to monitor INR for a resident who has been stabilized on warfarin and exhibits no signs of bleeding.
• Facility failure to identify and take action for minor symptoms of allergic response to medications, such as a rash.

• Facility failure to monitor for response to therapy or emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring thyroid function in resident receiving thyroid replacement hormone and monitoring hydration status and basic metabolic profile for residents receiving diuretics or ACE inhibitors).

**Severity Level 1: No actual harm with potential for minimal harm**

The failure of the facility to provide appropriate care and services to manage the resident’s medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, severity level 1 does not apply for this regulatory requirement.
INTENT (F425) 42 CFR 483.60(a)(b)(1)

The intent of this requirement is that the facility implements a system to accurately and safely provide or obtain pharmaceutical services, which includes the provision of routine and emergency medications, biologicals and consultation of a licensed pharmacist in order to meet the needs of the residents. The system involves at a minimum:

- Consulting with the licensed pharmacist to establish, implement, and evaluate procedures that govern all aspects of pharmaceutical services for and within the facility;
- Accurately acquiring, receiving, storing, controlling, dispensing, administering, and disposing of medications in accordance with applicable requirements and standards of practice;
- Providing routine and emergency medications timely to meet each resident’s needs;
- Performing and reporting the results of a medication regimen review (MRR) for each resident at least monthly and taking action on the identified irregularities; and
- Utilizing only persons authorized by state requirements to administer medications.

NOTE: Although the regulatory language refers to “drugs,” the guidance in this document generally will refer to “medications” rather than “drugs,” except in those situations where the term “drug” has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident’s medication regimen for effectiveness and safety.

- “Acquiring medication” – refers to the process by which a facility requests and obtains a medication
- “Administering medication” – refers to the process of assuring the delivery of the right medication(s) via the intended route to the right person, in the right dose and at the right time.
- “Biologics” – are products isolated from a variety of natural sources—human, animal, or microorganism—or produced by biotechnology methods and other cutting-edge technologies and may include a wide range of products such as
vaccine, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

- “Dispensing” – refers to the interpretation of a prescription, selecting, measuring and packaging or repackaging of the product (as necessary), and labeling the medication or device pursuant to that prescription.

- “Pharmacy assistants or technicians” – refers to the ancillary personnel who work under the supervision and delegation of the pharmacist consistent with state law and regulations.

- “Receiving medication” – refers to the process of accepting a medication from a source (e.g., vending pharmacy delivery agent, VA, family member).

OVERVIEW

As the majority of nursing home residents require medications for the management of conditions, the facility must develop and implement a system that provides for the timely acquisition and safe use of medications in accordance with the authorized prescriber’s orders, applicable state and federal laws and regulations, manufacturers’ specifications, characteristics of the resident population, individual resident condition, recognized standards of practice, and the facility’s established procedures. Employing or obtaining the services of a licensed pharmacist is required for the system to function effectively.

There are numerous recognized resources address different aspects of pharmaceutical services, such as:

- The American Society of Consultant Pharmacists (ASCP) www.ascp.com;

- The American Society of Health System Pharmacists (ASHP) www.ashp.com;

- The American Medical Directors Association (AMDA) www.amda.com;

- The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;

- US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) www.fda.gov/cder; and


NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services.
PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at F425 requires that the facility provide or obtain routine and emergency medications and biologicals for its residents in a timely manner in order to meet the needs of the resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hour situations. Delayed acquisition of a medication may negatively affect the timely administration and adversely affect the condition of the resident. A medication, whether prescribed on a routine, emergency, or as needed basis, should be administered in a timely manner. Factors that may help determine timeliness and guide the procedures for acquisition include:

- Availability of medications to provide continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;

- The condition of the resident such as severity or instability of his/her condition, a significant change in condition, discomfort, risks, active signs and symptoms, and the potential impact resulting from a delay in acquiring the medications;

- The category of medication, such as antibiotics, pain medication;

- The availability of medications in emergency supply, if applicable; and

- The desired/ordered start time for the medication.

SERVICES OF A LICENSED PHARMACIST

The facility is responsible for employing or contracting for the services of a licensed pharmacist who will provide consultation on all aspects of the provision of pharmacy services in the facility. The licensed pharmacist has an important role both in identifying potential irregularities which may influence care quality and in establishing procedures which minimize the risk and emphasize safety for the residents. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with an independent licensed pharmacist. Whatever the arrangement or method employed, the facility and the licensed pharmacist should identify how they will collaborate for effective consultation regarding pharmacy services, including:

- Assisting the facility to develop procedures for the provision of pharmacy services, including accurately acquiring, receiving, storing, controlling, dispensing, administering, and disposing of routine and emergency medications and biologicals as well as monitoring the emergency supply of medications;
• Providing oversight and consultation on all aspects of pharmacy services; and

• Assuring that a MRR is performed at least monthly for each resident in the facility. (See F428 for MRR guidance.)

NOTE: For purposes of this guidance, references to “the pharmacist” mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support the healthcare needs of the residents, that are consistent with current standards of practice, and that meet the regulatory requirements. The pharmacist helps coordinate and evaluate the pharmaceutical services within the facility by reviewing and evaluating aspects of resident care related to medication use, and helping the facility identify, evaluate, and address medication issues which may have an impact on the quality of care and quality of life of residents. This includes, but is not limited to, helping the facility:

• Assure that medications are requested, received and administered in a timely manner as ordered by the prescriber authorized to prescribe medications in accordance with state requirements such as: physicians, advanced practice nurses, physician assistants;

• Develop mechanisms for communicating, addressing, and resolving issues related to pharmacy services; and

• In collaboration with the medical director and facility staff, develop procedures and guidance regarding when to contact a practitioner regarding a medication issue and/or adverse effect and what type of information should be gathered prior to contacting the practitioner.

In addition, other areas for the pharmacist input to and collaboration with the facility may include:

• Providing ongoing guidance in the development and implementation of pharmaceutical procedures, including the review and revision of existing procedures;

• Recommending the type of medication delivery system, in order to minimize the use of different types of packaging, such as bottles, bubble packs, tear strips, and to decrease the possibility of medication errors;

• Providing feedback to facility management about performance and practices related to medication administration and medication errors;
• Interacting with the quality assessment and assurance committee when its work relates to medications, including medication errors;

• Reviewing individual resident medications or resident specific issues as they arise and are suspected to be related to medication therapy, when requested by the facility or as indicated;

• Recommending resources for staff to use for the identification of medications and information on contraindications, side effects and/or adverse effects, dosage levels and other pertinent information; and

• Identifying facility educational and informational needs and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents and families.

NOTE: This does not imply that the pharmacist must personally present educational programs.

PHARMACEUTICAL SERVICES PROCEDURES

The facility assures that the pharmacist:

• Collaborates with the facility in the development of procedures regarding the overall management of the pharmaceutical services;

• Helps assure that the procedures address the needs of the residents and reflect current standards of practice; and

• Guides, approves, and helps oversee the implementation of the procedures.

At a minimum, the facility procedures should address acquiring, receiving, dispensing, and administering medications as well as the labeling and storage of medications, using authorized personnel, and the provisions for MRR.

Accurate and Timely Acquisition of Medications

The facility procedures should address acquisition of medications, such as:

• Availability of a supply of emergency medications, if allowed by state law, including the types or categories of medications, amounts on hand, dosages to be provided, location of the supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, and the steps for replacing the supply when dosages are used;
- Identify when, how and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting pharmacy for an original routine medication order, emergency medication order, and for refills;

- The availability of medications when needed. In order to facilitate timely administration, the medication is either in the facility or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;

- How and when to reconcile medication orders including telephone orders, monthly or other periodic recapitulations, medication orders to (and receipt of medications from) the pharmacy, and MAR, including who may transcribe practitioners orders and enter the orders onto the MAR; and

- When, how and who may contact the physician to verify or clarify an order or for direction when delivery of a medication will be delayed or the medication is not or will not be available (e.g., clarification when the resident has allergies to or there are contraindications to the medication being ordered, when the medication will not be available the day it was ordered, delay in acquisition of the medication may have a negative impact on the condition of the resident, alternative medications that are accessible or may be used if a medication is not available).

**Receiving Medication(s)**

Procedures addressing receipt of medications should:

- Identify how the receipt of medications from dispensing pharmacists (and/or family members, where permitted by law) will occur and how receipt will be reconciled with the practitioner’s order and the requisition for the medication;

- Define the staff authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and

- Define the responsibility to assure medications are incorporated into the resident’s specific allocation/storage area.

**Dispensing medication(s)**

Procedures should address the facility’s expectations of the in-house pharmacy or arrangements between the outside dispensing pharmacy(ies) and the facility regarding:

- Delivery and receipt;

- Labeling; and
• The type of medication delivery system used in the facility to assure compatible and safe medication delivery and to minimize medication administration errors.

**Administering medications**

The implementation of procedures which are consistent with current standards of practice promotes the accuracy of medication administration and avoidance of medication errors and facilitates proper medication use and the security of medications. These procedures should address, but not be limited to:

• Staff workload to provide for safe medication administration without unnecessary interruptions;

• How and to whom medication errors are to be reported, including errors caused by the wrong medication, dose, time, route and resident;

• Personnel authorized, consistent with state requirements, to administer the medications, including IVs, (see Authorized Personnel and Staff Qualifications section within this document);

• A system to assure the right medication in the right dose is administered, in accordance with manufacturers’ specifications and with standards of practice, to the right person via the right route in the right dosage form and at the right time;

• Allowing for adequate time to conduct medication passes so that time-sensitive medications are administered appropriately;

• Defining the schedules for administering medications to maximize the effectiveness and maintain appropriate serum concentrations (blood levels) for certain medications such as antibiotics, pain medications and to avoid potential medication interactions such as medication-food or medication-medication;

• Defining general guidelines for the timing of specific monitoring related to medications when ordered or indicated such as blood pressure, pulse, blood sugar, weight, on a weekly or daily basis, or before administering the medication, and establishing parameters for notifying the prescriber of concerns;

• Techniques and precautions for administering medications through alternate routes such as eye, ear, buccal, injection, IV, atomizer/aerosol/ inhalation therapy, nasogastric (NG) or gastric tubes (G-tubes or PEG tubes), including monitoring for potential adverse outcomes and/or effectiveness of the treatment(s);

• Documentation that the resident received the medication(s); and

• Provisions for accessible product information.
Procedures should also address the need to clarify any order that is incomplete, illegible, or presents any other concern, prior to dispensing or administrating the medication.

**Labeling and Storage of Medications, including Controlled Substances**

Procedures that assure accurate and complete labeling of the medications (including appropriate accessory instructions) consistent with state and federal requirements minimize opportunities for error. The procedures should define, at a minimum:

- The content of the label for bulk medication and the unit dose packaging;
- How the facility will label and assure the integrity of multi-dose vials, considering the manufacturer’s specifications;
- How to handle order changes that affect labeling; and
- How to handle confusing or incomplete labels.

The procedures addressing the safe storage of medications should include:

- Locking and access to keys for the medication rooms and carts;
- Location;
- Temperatures of the storage area(s) including the medication room(s), refrigerators and other areas;
- Other issues related to storage in order to maintain the integrity of the medications;
- A system of records of receipt and disposition of all controlled substances (including a record of all controlled substances in such a manner that the accounting is maintained);
- Periodic reconciliation of controlled substances;
- Provision of a separately locked permanently affixed compartment for storage of Schedule II controlled substances and other medications subject to abuse; and
- Which personnel, in addition to those who administer medications, are authorized to have access to medications, such as pharmacy technicians or assistants.

For additional detail regarding labeling, storage, and controlled substances see the guidance at F431.
Staff Qualifications/Training

Procedures addressing staff qualifications should include, for example:

- How the facility assures ongoing competency of staff authorized to administer medications;

- If used, how temporary, agency, or on-call staff, are trained, monitored, and evaluated to assure competency in the proper administration of medications and biologicals;

- Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:
  - IV pumps or other IV delivery systems including calculating dosage, infusion rates and total fluid absorbed, and compatibility of medications to be added to the IV;
  - Blood glucose meters, including calibration, cleaning between individual residents; and
  - Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, pill crushers.

Medication Regimen Review

The procedures should address the content of the review, including:

- The clinical indication and goals for the use of the medication (including condition(s) being treated);

- Consideration of the benefits and risks, including the side effects of the medication, the resident’s allergies, the potential for interaction with other medications or food;

- Whether the dose, frequency, route of administration and duration are consistent with the resident’s condition, manufacturer’s recommendations, and standards of practice;

- Progress toward or maintenance of the goal(s) for the medication therapy;

- Potential for or emergence of adverse consequences that may be identified through review of laboratory results, other diagnostic studies, or other measurements (such as bowel function, intake and output);
The medication regimen as a potential contributing or causative factor, if the resident experiences a medication related problem, a decline, or a new symptom;

Other irregularities, including medication errors; and

Timeliness, who may conduct the review, and documentation and location of the results of the review; and

NOTE: The results of the review are part of the clinical record and should be readily available to the attending physician, director of nursing, pertinent facility staff, medical director (when indicted), surveyors, and resident or the legal representative.

Any follow up action. The facility should have a procedure and/or system to address irregularities identified in the MRR, lab values or other reports indicating a potential problem(s) that requires urgent attention, because it may cause serious harm, injury, or death, if not addressed immediately.

AUTHORIZED PERSONNEL

The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse. The facility assures that all persons administering medications in the facility are qualified and oriented to the facility’s procedures and have access to current information regarding medications being used within the facility, including side effects of medications, contraindications, doses, etc.

INVESTIGATIVE PROTOCOL

PHARMACY SERVICES: LICENSED PHARMACIST AND SYSTEMS FOR AVAILABILITY AND SAFE USE OF MEDICATIONS

Objectives

To determine whether the facility uses the services of a licensed pharmacist; and

To determine whether the facility has the structure and processes in place to provide timely and safe medication use for each resident.

Use

Throughout the course of the survey, be alert to triggers which indicate that additional review is necessary regarding the availability of medications; acquiring medication(s) accurately and timely; receiving, dispensing, administering, labeling and storage of
medications, including controlled substances; and the use of qualified, authorized personnel.

**Procedures**

If concerns have been identified for the requirements addressing any of the required components related to safe medication use, pharmacist consultation, or the use of qualified staff to administer medications, review the facility’s evidence that they have been receiving ongoing pharmacy consultation regarding all aspects of the provision of pharmacy services in the facility, including identification of problems and recommendations for potential corrective actions.

Review procedures related to the triggered area(s) and interview staff or the pharmacist regarding the areas of concern. For example, if medications are not administered in a timely manner:

- Interview the director of nursing and one or more of the staff responsible for passing medications to determine if they are aware of the delay(s) in administration in order to identify the root causes for the delay.

- Also, as necessary:
  - Review the staffing patterns for sufficient qualified staff to pass medications;
  - Review the procedures for scheduled times of administration;
  - Determine the type of medications that are not being passed on a timely basis, such as antibiotics or other time sensitive medications;
  - Interview the pharmacist to determine if the concern regarding timely administration was identified and if the pharmacist had made recommendations to facility staff in order to address the concern; and
  - Interview facility staff regarding the response to the pharmacist’s report, if any.

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**

**Synopsis of Regulation (F425):**

The Pharmaceutical Services, Procedures and Consultation requirement has four aspects. First, the facility must provide routine and/or emergency medications and biologicals or obtain them under an agreement described in 42 CFR 483.75(h) of this part. Second, the facility must have procedures for pharmaceutical services to meet the resident’s needs. The procedures must assure accurate acquiring, receiving, dispensing and administering...
of all medications and biologicals. Third, the facility must have a licensed pharmacist provide consultation and oversee all aspects of the pharmaceutical services and conduct medication regimen reviews for each resident. Fourth, the facility must follow applicable laws and regulations about who can administer medications.

**Criteria for Compliance**

Compliance with 42 CFR 483.60, F425, Pharmaceutical services

The facility is in compliance with this requirement, if they provide or arrange for:

- Each resident to receive medications and/or biologicals as ordered by the practitioner;
- The development and implementation of procedures for the pharmaceutical services;
- The services of a licensed pharmacist to provide consultation for all aspects of pharmaceutical services; and
- Appropriate personnel to administer medications, consistent with applicable state law and regulations.

If not, cite at F425.

**Non-compliance for F425**

After completing the Investigative Protocol, analyze the data and review the regulatory requirement in order to determine whether or not compliance with F425 exists. As the requirements for F425 include both process and structural components, a determination of non-compliance with F425 does not require a finding of harm to the resident. If the survey team identifies non-compliance at other tags which may be related to the roles and responsibilities of the pharmacist or the provision of pharmacy services, the team must also decide whether there is non-compliance with this requirement. Non-compliance for F425 may include (but is not limited to) the facility failure to:

- Utilize the services of a licensed pharmacist.
- Ensure only appropriate personnel administer medications.
- Provide medications and/or biologicals to meet the needs of the resident.
- Develop or implement procedures for one or more of the following: acquiring, receiving, dispensing or administering medications.
• Develop or implement a procedure to identify and resolve irregularities between the pharmacist visits.

• Develop a procedure for the MRR.

• Develop or implement procedures to administer medications by the proper route.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F425 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care.

   Non-compliance related to actual or potential harm/negative outcome for F425 may include, but are not limited to:

   • As a result of the lack of licensed pharmacist involvement in the development of procedures for the scheduling for medication administration residents did not receive maximum benefit of medications which were time sensitive.

   • As a result of the facility’s failure to provide medications needed by a resident in a timely manner, the resident continued to experience pain or worsening symptoms of the condition.

   • As a result of the use of unauthorized personnel to administer medications, residents received medications in error.

2. Degree of harm (actual or potential) related to the non-compliance.

   Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

   • If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort.

   • If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required.
Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F425. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident’s health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety

Immediate Jeopardy is a situation in which the facility’s non-compliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Severity Level 4 (Immediate Jeopardy) deficiency at another tag (e.g., F329, F333, F428) and the non-compliance is related to a failure of the pharmaceutical services system to establish procedures for monitoring of medications with a significant potential for adverse consequences.

- There is no licensed pharmacist and/or the facility and/or licensed pharmacist failed to assure that the pharmaceutical services system included:
  - An effective system to assure medications were available timely for a recently admitted resident requiring pain medication resulting in the resident complaining of excruciating pain (e.g., a pain score of 9 on a 10-point scale);
  - Assuring that equipment used to administer medications was in appropriate working order (such as calibrating glucometers) leading to an adverse consequence at the immediate jeopardy level;
o Securing and limiting access to medications to assure that residents who should not have access to medications did not have access. This resulted in a resident ingesting medications not intended for that resident leading to an adverse consequence at the immediate jeopardy level; and

o Developing and implementing procedures about when and how to notify the attending physician when a medication irregularity was discovered that required urgent attention. This resulted in the physician not being notified and the resident experiencing an irreversible, incapacitating adverse consequence.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates non-compliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being.

Examples may include, but are not limited to:

- Severity Level 3 deficiency at another tag (e.g., F329, F333, F428) and the non-compliance is related to a failure of the pharmaceutical services system such as a lack of guidance about developing and implementing procedures for monitoring medication therapy resulting in a failure to monitor anti-diabetic therapy and the resident experiencing harm.

- There is no licensed pharmacist and/or the facility and/or licensed pharmacist failed to assure that the pharmaceutical services system included:
  
  o A procedure/mechanism in place to assure that medication orders are accurate and consistent across the entire process for ordering and administering medications (such as transfer orders, admission orders, telephone orders, order renewals, and the MAR). This led to an adverse consequence at level 3 harm as the result of a wrong dose of a medication being given (such as spontaneous bruising and epistaxis requiring intervention as a result of the wrong dose of warfarin being administered); and

  o Provisions to assure that staff are trained or competent in the use of new equipment (e.g., I.V. pump). This resulted in a resident receiving an excessive or subtherapeutic dose of medication resulting in exacerbation of a condition, continuation of treatment, and hospitalization.
NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples may include, but are not limited to:

- Severity Level 2 deficiency at another tag (e.g., F329, F333, F428) and the non-compliance is related to a failure of the pharmaceutical services system such as a failure of licensed staff to supervise medication administration by authorized unlicensed personnel, and errors occurred in the timely provision of oral antibiotic therapy.

- There is no licensed pharmacist and/or the facility and/or licensed pharmacist failed to assure that the pharmaceutical services system included:
  - The development and implementation of a procedure for the MRR results to be shared with the attending physician, resulting in the attending physician not being notified of the continued administration of a medication that has a low incidence of minor side effects. The resident had not experienced any harm, although the potential for harm was present if no intervention was implemented; and
  - Procedures for reordering medications when the supply runs low and for timely acquisition of medications to meet the needs of the residents. This resulted in a resident not receiving medication for heartburn for seven days and experiencing a return of minor symptoms of heartburn. The level of discomfort did not interfere with the resident’s participation in or performing activities of daily living.

Severity Level 1 Considerations: No actual harm with potential for minimal harm

In order to cite no actual harm with potential for minimal harm at this tag, the surveyor must verify that no resident harm or potential for more than minimal harm identified at other requirements was related to lack of pharmacy services, absence of or failure to implement pharmacy procedures, or absence of oversight by the licensed pharmacist.

Examples of non-compliance for severity level 1 may include:
• The facility and/or licensed pharmacist failed to:
  
  o Coordinate pharmacy services with no negative resident outcomes as a result of that deficient practice; or
  
  o Implement pharmacy procedures but there were no negative resident outcomes as a result of that deficient practice.

• There is no licensed pharmacist; and
  
  o There are no negative resident outcomes related to pharmacy services; and
  
  o Pharmacy procedures and systems are in place; and
  
  o The facility is actively seeking a new licensed pharmacist.

• There was a short term failure to provide medications that pose minimal risk to the resident, such as a routine order for a daily multi-vitamin.
INTENT (F428) 42 CFR 483.60(c)(1)(2)

The intent of this requirement is that each resident’s regimen of medications is reviewed at least monthly or more frequently depending upon the resident’s condition and the nature of the medications in order, to the extent possible, to maintain the resident’s highest practicable level of functioning and prevent or minimize adverse consequences related to medication therapy. The medication regimen review (MRR) is an integral component of the facility’s pharmaceutical services system involving a comprehensive review of the medications by a licensed pharmacist, the identification and reporting of irregularities to the attending physician and the director of nursing, and action taken in response to the irregularities identified.

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident’s medication regimen for effectiveness and safety.

- “Adverse consequences” – An effect that is due to or associated with a medication and that is manifested as an unpleasant symptom, or that impairs or causes a decline in an individual’s health, physical condition, or functional or psychosocial status. It may include various types of adverse drug reactions and interactions.

- “Dose” – The total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

- “Excessive dose” (including duplicate therapy) – means the total amount of any medication given at one time or over a period of time that is greater than the amount recommended by the manufacturer’s label or package insert, or by standards of practice for a resident’s age and condition; there is no evidence of a review for the continued necessity of the dose or of attempts at, or consideration of the possibility of, tapering a medication; and there is no documented clinical rationale for the benefit or necessity for the dose or for use of multiple medications from the same class.

- “Duration” – The total length of time the medication is being received.

- “Excessive Duration” – means the medication is administered beyond the manufacturer’s recommended time frames or facility established stop order policies; beyond the length of time advised by current standards of practice; or when there is no additional therapeutic benefit being derived and no clear clinical factors present that would warrant the indefinite use of the medication.
• “Irregularity” – refers to any event related to the ordering, acquiring, dispensing, receiving, storing, controlling, timing, administration, documentation, reporting, or monitoring of a medication, which can actually or potentially interfere with the intended outcome for a resident and can include, but is not limited to a medication related problem.

• “Medication Regimen Review” – is a comprehensive assessment of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse drug/medication outcomes or adverse drug reactions. 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.

• “Monitoring” – The ongoing collection and analysis of information (including observation and diagnostic test results, etc.) and comparison to baseline data in order to: a) ascertain the individual’s response to treatment and care, including progress or lack of progress toward a therapeutic goal and detection of any complications or adverse consequences of the condition or of the treatments; and b) support decisions about modifying, discontinuing, or justifying the continuation of any intervention.

• “Pharmacy Assistant or Technician” – refers to ancillary personnel who work under the supervision and delegation of the pharmacist as consistent with state law.

• “Side Effect” – An expected, known reaction that occurs with a predictable frequency and is less intense or problematic than an ADR. Side effects of minimal impact or duration do not necessarily constitute adverse consequences. Consideration of side effects may be a key factor in selecting particular medications.

OVERVIEW

Many residents in the nursing home require multiple medications to address their conditions often making medication therapy complex. Medications are used for their therapeutic benefits in diagnosing and managing/treating acute and/or chronic conditions, maintaining and/or improving functional status, and improving or sustaining the resident’s quality of life. The populations of nursing homes may be quite diverse and include not only geriatric residents, but also residents with special needs, such as residents with immuno-compromised conditions, end stage renal disease, spinal cord or closed head injuries, or children. Regardless, the population of nursing homes has been identified as having a high risk for adverse consequences related to medications.

As some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition, it is important for the facility’s pharmaceutical services system to provide an ongoing assessment of the resident’s medication regimen in
order to facilitate the identification of possible medication related concerns. By virtue of
the pharmacist’s understanding of the nature of medications and the cautions, actions and
interactions of medications as well as current medication advisories, the pharmacist
conducts the medication regimen review (MRR), provides consultation regarding the
medication regimen, and is an important member of the interdisciplinary team.
Regulations prohibit the pharmacist from delegating the medication regimen reviews to
ancillary staff.

Some resources are available to facilitate evaluating medication concerns related to the
performance of the MRR, such as:

- The American Society of Consultant Pharmacists (ASCP) www.ascp.com;
- The American Medical Directors Association (AMDA) www.amda.com;
- The National Coordinating Council for Medication Error Reporting and
  Prevention (NCCMERP) www.nccmerp.org;
- The U.S. Department of Health and Human Services, Food and Drug
  Administration (FDA) www.fda.gov/cder; and
- DHHS, CMS Sharing Innovations in Quality website at

NOTE: References to non-CMS sources or sites on the Internet are provided as a
service and do not constitute or imply endorsement of these organizations or
their programs by CMS or the U.S. Department of Health and Human
Services. CMS is not responsible for the content of pages found at these sites.
URL addresses were current as of the date of this publication.

This guidance is not intended to imply that all adverse consequences related to
medications are preventable, but rather to specify that a system exists to assure that
medication usage is evaluated on an ongoing basis, that potential problems are identified
and acted upon, and that medication-related problems are considered when the resident
has a change in condition. This guidance will discuss the following aspects of the
facility’s MRR component of the pharmaceutical services systems:

- The review of the resident’s medication regimen, by a licensed pharmacist, to
  identify and report irregularities; and

- Acting upon identified irregularities in order to minimize or prevent potential or
  actual adverse consequences, to the extent possible.

For the purposes of this guidance, when the guidance refers to “the pharmacist”, this
means the licensed pharmacist, whether employed directly by the facility or through
arrangement.

NOTE: This guidance is not intended to instruct surveyors to direct the medication
therapy.
MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident’s medication regimen. The pharmacist must review each resident’s medication regimen in order to identify potential or actual irregularities; and to the extent possible, to identify potential and/or emerging or actual adverse consequences resulting from or associated with medications. Availability of technology such as electronic clinical records, electronic medication records, may allow the pharmacist to conduct some components of the review outside the facility; however, important information may need to be obtained during interviews and observations of the resident in order to identify potential adverse drug consequences, the nature and extent of the medication irregularity, such as the presence of symptoms related to tardive dyskinesia, feelings of dizziness, anorexia, or falls. For the surveyor, the pharmacist may be contacted to provide information regarding the resident’s medication regimen regarding the use of the resident’s medications and actions.

Information in the resident’s record that may contain information regarding possible and/or actual medication irregularities, includes, but is not limited to, the medication administration record (MAR); prescriber’s orders; progress, nursing and consultants notes; the Resident Assessment Instrument (RAI) for functional declines or clinical conditions that warrant medication use or signs of medication related problems; Quality Indicator reports; laboratory reports; and other sources that provide information regarding behavioral monitoring and/or changes. The pharmacist may also obtain information on medication use or concerns from the attending physician, facility staff, and, potentially interviewing and/or observing the resident. Important aspects of the MRR include, timeliness, identification of irregularities, the location of the review, notification of findings and the identification of medication errors, if any. This guidance discusses these aspects and also provides a table of medication interactions.

Timeliness of the Medication Regimen Review

The facility’s pharmaceutical services system relies on the pharmacist to conduct a medication review of each resident at least once a month, or approximately every thirty (30) days. The review will be considered timely if it occurs no later than ten (10) days after the date the review was required. This does not mean that the date of the review may continue to be delayed back ten days, but that it provides a ten-day grace period around the date of the required review. In addition, there may be situations when it may be necessary for the pharmacist to conduct the MRR at shorter intervals such as initially for residents who stay in the facility less than 30 days or when the resident experiences an acute change of condition that may be related to the medication regimen.

Identification of Irregularities

The overall objective of the MRR is to identify irregularities including (but not limited to) syndromes potentially related to medication therapy, emerging or existing adverse drug consequences, as well as the potential for adverse drug reactions and medication
errors (to the extent possible), in order to try to minimize or prevent adverse consequences. The review provides information about:

- Whether indications for use are supported by appropriate objective findings, diagnosis and/or symptom;
- Presence of side effects, allergies, and interactions with medication and food;
- The dose, frequency, route of administration and duration of each prescribed medication being appropriate for the resident’s age and condition;
- Potentially significant medication interactions for each resident, such as medication-medication, medication-food, medication herbal substances interactions;
- Laboratory results as applicable;
- Outcomes of medication therapy;
- Recent changes in the resident’s condition that may be related to medications. Examples of changes related to medication use that could occur at any age, but are more common in the geriatric population, include:
  - Altered mental status (including delirium or excessive somnolence);
  - Anorexia and/or unplanned weight loss, or weight gain;
  - Gastrointestinal bleeding;
  - Falls, dizziness, or evidence of impaired coordination;
  - Urinary retention or incontinence;
  - New cognitive decline, or worsening of dementia;
  - Constipation;
  - Insomnia or sleep disturbance;
  - Seizure activity; and
  - Behavioral changes, including increased distressed behavior.

In reviewing for irregularities, the pharmacist may identify and document concerns in one or more of the following categories:ii (See F329 for additional discussion of irregularities relating to dose, duration, indications for use, monitoring and adverse consequences.)
• Medication use without adequate indications for use refers to orders for or use of a medication without a medically valid indication for use.

• Improper medication selection refers to the absence of or inadequate justification for selecting a medication to treat a medical or psychiatric condition, when safer or more clinically appropriate alternatives exist.

• Inadequate effectiveness of medication indicates that an appropriate medication is not reaching the intended treatment goals for reasons such as timing of administration, dosing intervals or sufficiency of dose, or techniques of administration.

• Excessive dose or duration places the resident at greater risk for adverse consequences, although the resident may not have yet experienced an adverse consequence.

• Adverse drug reaction (ADR) is a form of adverse consequences and may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or therapy. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect may not always rise to the level of being an ADR. The following may reflect an adverse consequence caused by or associated with a medication:
  
  o A change in condition;
  
  o A new sign, symptom, or problem, especially one that is not otherwise attributable to an underlying physical or functional cause;
  
  o A worsening of an existing problem;
  
  o An otherwise unexplained decline in function or cognition; or
  
  o A non-specific sign or symptom that is not otherwise attributable to an underlying physical or functional cause.

• Medication use without adequate monitoring may involve absence of review of the resident’s response to the medication(s) including progress toward the treatment goals for use of the medication or presence of emerging or existing adverse consequences and lack of or inadequate response to the findings.
Medication interaction refers to an undesired event that occurs because of the simultaneous presence of a medication and other factors. Such interactions may include medication-medication, medication-food, medication-herbal product or medication-laboratory test interaction that may result in an actual or potential medical problem. The following table addresses four medications that tend to be problematic in the long term care population because of interactions: warfarin, ACE Inhibitors, digoxin, and theophylline.

**Common Medication-Medication Interactions in Long Term Care**

These examples represent an overview of the more common interactions seen in long-term care and are not meant to be all inclusive:

<table>
<thead>
<tr>
<th>Medication 1</th>
<th>Medication 2</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin (Coumadin)</td>
<td>NSAIDs such as ibuprofen and naproxen (excluding COX-2 inhibitors)</td>
<td>Potential for serious gastrointestinal bleeding</td>
</tr>
<tr>
<td>Warfarin (Coumadin)</td>
<td>Sulfonamides such as trimethoprim/sulfamethoxazole (Bactrim)</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>Warfarin (Coumadin)</td>
<td>Macrolides such as clarithromycin (Biaxin), erythromycin</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>Warfarin (Coumadin)</td>
<td>Fluoroquinolones such as ciprofloxacin (Cipro), levofloxacin (Levaquin), ofloxacin (Floxin)</td>
<td>Increased effects of warfarin, with potential for bleeding</td>
</tr>
<tr>
<td>Warfarin (Coumadin)</td>
<td>Phenytoin (Dilantin, Phenytek)</td>
<td>Increased effects of warfarin and/or phenytoin</td>
</tr>
<tr>
<td>ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril</td>
<td>Potassium Supplements</td>
<td>Elevated serum potassium levels</td>
</tr>
<tr>
<td>ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril</td>
<td>spironolactone (Aldactone)</td>
<td>Elevated serum potassium levels</td>
</tr>
<tr>
<td>Digoxin (Lanoxin)</td>
<td>Amiodarone (Cordarone, Pacerone)</td>
<td>Digoxin toxicity</td>
</tr>
<tr>
<td>Digoxin (Lanoxin)</td>
<td>Verapamil (Calan, Covera-HS, Isoptin)</td>
<td>Digoxin toxicity</td>
</tr>
<tr>
<td>Theophylline</td>
<td>Fluoroquinolones such as ciprofloxacin (Cipro), levofloxacin (Levaquin), ofloxacin (Floxin)</td>
<td>Theophylline toxicity</td>
</tr>
</tbody>
</table>
NOTE: Concomitant use of these medication combinations is not necessarily inappropriate and these examples are not intended to be absolute contraindications for using the two medications together. Many times two medications with a documented interaction can be used together safely. However, if these medications are used together, diligent monitoring is warranted to prevent harm to the resident.

Location of Medication Regimen Review

On the day the medication review is conducted, the pharmacist is expected to document within the report either that no irregularity was identified or the nature of the irregularity(ies), if any were identified. The pharmacist’s report is considered part of each resident’s clinical record. If it is not physically part of the active record, it must be maintained within the facility and be readily available for review. The interdisciplinary team is encouraged to review the reports to get the pharmacist’s input on resident problems and issues. Establishing a consistent location for the pharmacist’s report facilitates communication of the pharmacist’s findings and recommendations for review by the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR 483.10(b)(2),(d)(2)), ombudsman (with permission of the resident in accord with 42 CFR 483.10(j)(3)), and surveyors.

Notification of Findings of Medication Regimen Review

The pharmacist is responsible to notify the attending physician and director of nursing of identified irregularities and to provide a report of the findings. The facility and the pharmacist may collaborate to develop the most effective means for assuring appropriate notification. The notification may be done electronically, depending upon the technology within the system. The timeliness of the notification regarding the irregularities depends on the potential for or presence of serious harm, such as notifying the attending physician and director of nurses immediately in cases of bleeding in a resident on anti-coagulants or possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect.

Medication Errors

In the course of the review, the pharmacist may identify other concerns such as actual medication errors or the potential for errors which ultimately pose a risk to the resident. For example, a medication order transcribed incorrectly from the orders to the medication administration record (MAR) or transcribed incorrectly from a telephone order to the recapitulation/reorder of medications.

RESPONSE TO IRREGULARITIES IDENTIFIED IN THE MRR

Throughout this guidance, a response from a physician regarding a medication problem, implies appropriate communication, review, and resident management, but does not
imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.

It is important to note that in cases in which there is the potential for serious harm to occur and the attending physician does not concur with the report, the facility and the consulting pharmacist should contact the facility’s medical director for intervention to resolve the issue or follow the established facility procedure to resolve the situation when the attending physician and the medical director are the same. For those direct care issues that do not require physician medical interventions, such as recommendations regarding monitoring of vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

ENDNOTES

i American Society of Consultant Pharmacists (ASCP) Guidelines for Assessing the Quality of Drug Regimen Review in Long-Term Care Facilities


iii Top 10 Dangerous Drug Interactions in Long-Term Care presented by the Multidisciplinary Medication Management Project, a collaborative initiative of the American Society of Consultant Pharmacists (ASCP) and the American Medical Directors Association (AMDA).

REFER TO THE INVESTIGATIVE PROTOCOL AT F329 FOR EVALUATION OF MEDICATION REGIMEN REVIEW.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F428)

This requirement has four aspects relating to the safety of the resident’s medication regimen, including:
• A monthly (or more often as identified by the needs of the resident) medication regimen review by the pharmacist;

• The identification of any irregularities;

• A report to the attending physician and the director of nursing; and

• Action in response to the report of irregularities.

Criteria for compliance

Compliance with 42 CFR 483.60(c)(1) and (2), F428, Medication regimen review

The facility is in compliance with this requirement if:

• The pharmacist has performed a medication regimen review on each resident at least monthly (more frequently if the resident has had frequent changes in the medication regimen or the resident’s condition or nature of the medication regimen indicates) or at least initially for short stay residents;

• The pharmacist has identified existing irregularities and the potential for adverse consequences;

• The pharmacist has provided a report of the identified irregularities to the director of nurses and attending physician; and

• The report of these irregularities has been acted upon.

If not, Cite F428.

Non-compliance for F428

After completing the Investigative Protocol, analyze the data in order to determine whether or not compliance with F428 exists. A determination of non-compliance with F428 does not require a finding of harm to the resident. Non-compliance may include, but is not limited to, one or more of the following, including facility failure to:

• Provide a MRR by a pharmacist at least monthly (or more frequently, as indicated).

• Identify or report the absence of or inadequate indications for use of a medication with significant potential for adverse consequences or medication interactions.

• Recognize or evaluate signs or symptoms of a potential adverse consequence.

• Monitor the effectiveness of the medication therapy.
• Act upon the report of actual or potential for adverse consequences or other irregularities.

• Identify the absence of evidence explaining why or how the benefit of a medication with a high potential for severe adverse consequences outweighs the risk of a potential irregularity.

Potential tags for additional investigation:

If non-compliance with 483.60(c)(1) and (2) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether non-compliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when non-compliance has been identified include the following:

• 42 CFR 483.10(h)(11), F157, Notification of changes
  o Review whether the facility contacted the attending physician regarding a significant change in the resident’s condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as planned and/or indicated.

• 42 CFR 483.25(l), F329, Unnecessary medications
  o Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or is experiencing any adverse consequences.

• 42 CFR 483.40(a), F385, Physician supervision
  o Review if the attending physician supervised the resident’s medical treatment, including assessing the resident’s condition, identifying the need for medication, and ordering and providing ongoing review of the medication regimen to address the resident’s needs and identify and address adverse consequences related to medications.

• 42 CFR 483.40(b), F386, Physician visits
  o Review if the attending physician or designee reviewed the resident’s total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit as required by that regulation.

• 42 CFR 483.60(a)(b)(1), F425, Pharmacy services
Review whether the consulting pharmacist has provided consultation regarding all aspects of the pharmacy services, including the availability, effectiveness, and adverse consequences of medications, and procedures governing pharmaceutical services.

- 42 CFR 483.75(i), F501, Medical director
  
o Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a lack of response to identified or reported potential medication irregularities and adverse consequences.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident. The survey team must identify whether non-compliance cited at other tags (e.g., F329, F332/333) was the direct result of or related to inadequate or absent MRR or response to notification regarding irregularities.

The key elements for severity determination for F428 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate medication regimen review, reporting, or response to report.

   Non-compliance related to an actual or potential harm/negative outcome for F428 may include, but is not limited to:

   - The impact of the medication use prevented the resident from maintaining or improving his or her functional status and activities of daily living.

   - The resident experienced a serious adverse consequence related to a medication.

   - Irregularities within the medication regimen or accuracy of medication related documents created the potential for adverse consequences such as overdose, respiratory depression, rash or anorexia.

2. Degree of harm (actual or potential) related to the non-compliance.

   Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:
• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

• If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F428. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident’s health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility non-compliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety

Immediate Jeopardy is a situation in which the facility’s non-compliance with one or more requirements of participation:

• Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of the facility’s non-compliance that may cause or contribute to negative outcomes may include, but are not limited to:

• The pharmacist’s MRR failed to identify and report that a fentanyl skin patch and concomitant use of certain other medications, such as itraconazole or clarithromycin, substantially increased the risk of prolonged adverse consequences and may cause potentially fatal respiratory depression.

• Although the pharmacist identified irregularities with the potential for serious harm or death, the report was not provided to the physician or the report was not acted upon.
• Findings of non-compliance at Severity Level 4 at tag(s) F329 or F332/F333 that show evidence of process failures associated with the pharmacist’s responsibility for conducting the MRR.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates non-compliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being. Examples of harm include, but are not limited to:

• The pharmacist’s MRR failed to identify that the physician orders contained a standing order to crush medications as necessary and that a medication was being improperly administered causing the resident to experience significant adverse effects (such as abnormal bleeding or gastro-intestinal ulcers) requiring treatment (e.g., bisphosphonate being crushed).

• Repeated or cumulative failure of the pharmacist’s MRR to identify existing medication irregularities during medication review resulting in one or more residents experiencing harm (e.g., duplicative serotonin reuptake inhibitors leading to serotonin syndrome or excessive doses of antipsychotics leading to the emergence of movement disorders such as tardive dyskinesia).

• The pharmacist’s MRR failed to identify and report that the timing of a medication administration resulted in a failure of the resident to achieve or maintain the highest practicable level of functioning (such as scheduling the administration of diuretics close to bedtime resulting in nocturnal incontinence).

• Findings of non-compliance at Severity Level 3 at tag(s) F329 or F332/F333 that show evidence of process failures associated with the pharmacist’s responsibility for conducting the MRR.

NOTE: If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy

Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident’s ability to maintain or reach his or her highest practicable level of well being. The potential exists
for greater harm to occur if interventions are not provided. Examples include, but are not limited to:

- The pharmacist identified and reported that the resident’s condition had not improved in accordance with the expected therapeutic goal of the medication and that the number of medications remaining from the dispensed amount indicated the medications were not being administered. The facility failed to respond to the notification and the resident continued to complain of mild gastric discomfort.

- The pharmacist’s MRR did not identify that a medication (ferrous sulfate) was not being administered as ordered (with meals), but was being administered mid-morning without food and although the resident had been complaining of a decreased appetite since shortly after initiation of the medication, the resident had not yet lost weight.

- Findings of non-compliance at Severity Level 2 at tag(s) F329 or F332/F333 that show evidence of process failures associated with the pharmacist’s responsibility for conducting the MRR.

**NOTE:** If severity level 2 (No actual harm with potential for more than minimal harm that is not Immediate Jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 1 (no actual harm with the potential for minimal harm) exists.

**Severity Level 1 Considerations: No actual harm with potential for minimal harm**

Level 1 indicates that no resident harm has occurred or there is a potential for no more than minimal harm. Examples may include, but are not limited to:

- The pharmacist failed to conduct an MRR or the facility failed to involve the pharmacist in the review of a resident’s medication regimen as required or appropriate; or the pharmacist failed to provide a report of the MRR, but the resident experienced no harm and there was no potential for more than minimal harm.

- The pharmacist conducted the medication review, identified an irregularity that has not resulted in a negative outcome and is of minimal consequence (such as a multi-vitamin not being given as ordered) and reported to the director of nursing and attending physician, but the DON and/or physician failed to act upon the report.
INTENT (F431) 42 CFR 483.60(b)(2)(3)(d)(e)

The intent of this requirement is that the facility has in place a functioning medication system that includes the services of a licensed pharmacist and provides for:

- Safe and secure storage (including proper temperature controls and limited access) and safe handling (including disposition) of all medication;
- Accurate labeling to facilitate consideration of precautions and safe administration of medications;
- Accurate and timely medication records and periodic reconciliation and accounting of all controlled substances; and
- Prompt identification of loss or diversion of controlled substances so as to minimize the time between actual loss or diversion and the detection and determination of the extent of loss or diversion.

DEFINITIONS refer to F425 and F428 for definitions

OVERVIEW

Due to the number and types of medications that may be used and the vulnerable populations being served, long term care facilities must have formal mechanisms for safely handling and controlling medications and for maintaining accurate and timely records pertaining to medications. The facility must use a licensed pharmacist to help establish and oversee these mechanisms or systems. This guidance addresses those portions of the pharmaceutical services system related to medication access and storage, appropriate security and safeguarding of controlled substances, and labeling of medications to assure that they are provided to the residents accurately and are stored safely.

NOTE: For purposes of this guidance, references to “the pharmacist” mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

MEDICATION STORAGE AND ACCESS TO MEDICATIONS

All medications must be secured in a locked storage area with access limited to licensed personnel and those authorized by facility management and policy or by state or federal law. Storage areas may include, but are not limited to, drawers, cabinets, rooms, refrigerators, carts, resident rooms, and boxes. Depending on how the facility locks and stores medications (for example, a locked cart stored in the room, or in locked cabinets, a locked refrigerator, or drawers within the room), access to a medication room may not necessarily provide access to the medications.
Access to medications can be controlled by keys, security codes or cards, or other technology like finger prints. If a key is used to lock Schedule II medications and other medications subject to abuse, that key cannot be the same key that is used to gain access to the non-scheduled medications. Exception: Controlled medications and those subject to abuse may be stored with non-controlled medications as part of a unit dose distribution system with unit dose packaging, if the supply of the medications is limited and a shortage would be easily detected. If other access systems are used like security codes, cards, or finger prints, the facility shall have a system to limit who has security access and when access is used.

During a medication pass, it is necessary that medications be kept under the direct control of the person administering the medications or locked in the medication cart. In addition, it is important that the facility have procedures for the control and safe storage of medications for those residents who can self administer medications.

In some facilities, pharmacy technicians or assistants may have been delegated the task of stocking medications; however, while these technicians may have access to the medications, they should not have access to the keys. Authorized facility staff are expected to monitor and safeguard medications, especially during delivery to the nursing units. Facility staff should have access to medications as a function of their job only if they are authorized by the facility to do so, in accordance with state and federal laws and regulations. Therefore, maintenance staff, receptionists, housekeeping staff, etc. would not be responsible for delivering, transporting, storing, or stocking medications that were delivered by a vendor. In addition, they should not have access to locked medication storage areas when medications are not stored in separately locked compartments within that storage area.

Because many medications can be altered by exposure to improper temperature, light, or humidity, it is important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturer specifications, state regulations, or standards of practice (e.g., United States Pharmacopeia (USP) standards).

**CONTROLLED SUBSTANCES**

The facility should have a system to account for the receipt and disposition of all controlled substances. This system includes, but is not limited to:

- Record of receipt of all Schedule II medications specifying the name and strength of the medication, the quantity received, and designating the name of the resident or the emergency medication supply (consistent with state law);

  **NOTE:** The facility may store some controlled medications in an emergency medication supply in accordance with state law. The system must
address the reconciliation and monitoring of this supply as well as the
supply for individual residents.

- Documentation of usage, which may include for example, the medication
  administration record, proof-of-use sheets, or declining inventory sheets;

- Documentation of disposition including destruction, wastage, return to the
  pharmacy/manufacturer, or disposal in accordance with applicable state law, and

- Periodic reconciliation of the records (generally, at least monthly or more
  frequently as defined by facility procedures).

The pharmacist is not required by these regulations to complete the reconciliation, but
rather to determine that there is an effective system to do so and that the facility has
completed the reconciliation according to its procedures and/or state laws and
regulations. Although this regulation does not set a time frame for reconciliation, this
system should identify how often, how, when, and by whom the reconciliation will be
done. The system should be capable of readily identifying loss or diversion of controlled
substances so as to minimize the time frame between the actual loss or diversion and the
time of detection and follow-up to determine the extent of loss. Because diversion can
occur at any time, the reconciliation should be done often enough to identify problems.
(Some state or other federal laws or regulations may specify the frequency of
reconciliation, which may be reflected in the facility’s procedure and practices.) If the
systems have not been effective in preventing or identifying diversion or abuse, the
pharmacist and the facility should review and revise the monitoring procedures, as
necessary, such as increasing the frequency of reconciliation efforts.

LABELING OF MEDICATIONS AND BIOLOGICALS

Labeling information must be based upon currently accepted pharmacy principles and
practices. Labeling should be consistent with applicable federal and individual state
requirements, and should include: the resident’s name, the medication name (generic or
brand) and strength, route of administration (if other than oral), appropriate instructions
and precautions (such as shake well, with meals, do not crush, special storage
instructions), and the expiration date. Medications may be provided via various types of
delivery systems, such as blister packs, punch cards, bottles, vials, patches, intravenous
(IV) or parenteral fluids, drops, and ointments. The label for a single-unit package of an
individual-dose or unit-dose contains the medication name, strength and volume (where
appropriate), expiration date, route if not oral (e.g., buccal, sublingual, IM, IV,
ophthalmic, otic). Whenever any medications are added to parenteral solutions,
piggyback medications are connected, the label indicates the name and volume of the
solution, resident’s name, infusion rate, name and quantity of each additive, date of
preparation, ancillary precautions and date after which the mixture must not be used.

State law may or may not permit use of bulk containers of over-the-counter (OTC)
medications for general use within the facility. If regulations permit the facility to stock
OTC medications in bulk containers, the containers must contain the original manufacturer’s or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date. If individual resident specific supplies of bulk OTC medications are used, the container must identify the resident and must contain the original manufacturer’s or the pharmacy-applied label. The facility may place the resident’s name on the medication container without requiring a pharmacist to do so, but this should not cover pertinent information on the container.

Due to the complexity and length/amount of instructions, some medications may be labeled “use as directed.” However, physician orders and the medication administration record would need to reflect the instruction details. In addition, a facility that allows the use of “as directed” on a label should have a procedure to ensure that the staff know how to utilize this labeling method safely.

The facility’s procedures should address how changes in the medication orders or directions will be communicated to the dispensing pharmacy and how labels will be changed, if necessary, consistent with state requirements. Regardless, only a pharmacist—not the nurse or other facility staff—may change the label.

The facility may use its quality assurance and assessment committee in collaboration with the pharmacist to develop procedures to safeguard medications during delivery, evaluate the effectiveness of the systems for notifying the pharmacist(s) of changes, and evaluate the effectiveness of the related pharmacy services consultation. For example, the committee might evaluate the delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies.

INVESTIGATIVE PROTOCOL

PHARMACY SERVICES: LABELING AND STORAGE OF MEDICATIONS AND CONTROLLED SUBSTANCES

Objectives

To determine whether the facility has implemented a system to provide for:

- Safe handling, storage, and disposition of medication;
- Storage at proper temperatures;
- Accurate labeling;
- Control and reconciliation of all controlled substances; and
- Timely identification of loss or diversion of controlled substances and those subject to abuse.
Use

Use this protocol for all initial and standard surveys and, as necessary, on revisits and abbreviated standard surveys (complaint investigations).

Procedures

During observation of the medication pass and reconciliation with the orders (see also Task 5A CMS form 803 regarding access, storage and controlled substances), determine whether:

- Medication records including prescriber’s orders and MAR (as well as record of the medication administration) are in order and accurate;
- Labeling of the medications (prescription and OTC) reflects requirements and pharmacy standards of practice;
- Medications are identified up to the point of administration;
- Medications and biologicals are accessible only to authorized staff;
- Controlled substances are in separately locked, permanently affixed compartments (or are a minimal amount of unit dose packages);
- Medications have been stored to retain their integrity, such as:
  - Multi-dose vials labeled per facility policy and manufacturer’s specification once use of the vial has been initiated;
  - Temperature, light, and humidity controls meet specifications for the medication;
  - Medications are administered prior to the expiration date;

If concerns are identified indicating potential problems, further review the area of concern through interview with facility staff, such as the director of nursing, and the consultant pharmacist. For example, if a potential problem has been identified regarding lack of reconciliation or loss of controlled substances:

- Review the facility procedure and a sample of the records of reconciliations, and compare the amount of medication available with the records accounting for the area of concern; and
- Interview the director of nursing and/or pharmacist regarding:
o Actual frequency of the reconciliation;

o How the facility investigates loss or inability to reconcile controlled substances;

o What action has been employed to address staff performance; and

o How the pharmacist has been involved in recognizing the situation and collaborating with the facility to review and update its practices and procedures.

**DETERMINATION OF COMPLIANCE (Task 6, Appendix P)**

**Synopsis of regulation (F431)**

This requirement has several aspects. The pharmacy services must:

- Provide for the safe and secure storage of medications which means that medications must be stored at proper temperatures and locked at all times (except under direct staff supervision);

- Limit access to medications to those staff for whom access is authorized;

- Label medications in accordance with labeling requirements and accepted standards of practice; and

- Have safeguards and systems in place to provide control and accounting for controlled substances.

**Criteria for Compliance**

Compliance with 42 CFR 483.60(b)(2)(3)(d)(e), F431, Labeling, Storage, and Controlled Substances

The facility is in compliance if:

- The facility safeguards medications by locking the medications and limiting access;

- Medication labeling identifies the medication’s name, strength, and expiration date, and provides all appropriate instructions for staff;

- Controlled substances are maintained in a separately locked system and are reconciled appropriately; and

- Medications are stored appropriately, including proper temperature controls.
If not, cite F431.

**Non-compliance for F431**

After completing the investigation, determine whether or not compliance with the regulation exists. Non-compliance for F431 may include (but is not limited to) the facility failure to:

- Store medications to preserve their integrity, for example allowing medications that should be stored between 40 and 86 degrees to either freeze or to reach temperatures in excess of 100 degrees.
- Provide accurate labeling with accessory instructions, thereby creating a potential for wrong medication to be administered or for correct medications to be given by the wrong route.
- Accurately reconcile controlled substances.
- Store medications properly or control access to medications; for example leaving medications on top of the medication cart enabling a resident to consume the medication.

**V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)**

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F431 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of failure to meet the pharmacy requirements.**

   Non-compliance related to an actual or potential harm/negative outcome for F431 may include, but is not limited to:

   - Failure to lock medications, increasing the likelihood of accidental ingestion by residents.
   - Inaccurate or incomplete labeling, creating the potential for one or more residents to receive the wrong medication or dose or the correct medication by the wrong route.
• Storing medications or vaccines at wrong temperatures resulting in their inactivation.

2. **Degree of harm (actual or potential) related to the non-compliance.**

Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

• If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. **The immediacy of correction required.**

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F431. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident’s health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

**NOTE:** The death or transfer of a resident, who was harmed or injured as a result of facility non-compliance, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the non-compliance which allowed or caused the immediate jeopardy.

**Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety**

Immediate Jeopardy is a situation in which the facility’s non-compliance with one or more requirements of participation:

• Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of the facility’s non-compliance that may cause or contribute to negative outcomes may include, but are not limited to:
• The facility failed to restrict access to medications resulting in serious injury or harm or death from ingestion of the medications or posed a significant risk to the health of the residents (e.g., warfarin, digoxin, antibiotics, anticonvulsants, antipsychotics) resulting in the potential for serious adverse consequences such as kidney or liver failure, anaphylactic shock, cardiac arrest) or death.

• As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication with a high potential for severe adverse consequences (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) which resulted in or had the potential for serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at severity level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates non-compliance that results in actual harm, and can include but may not be limited to compromise, decline, or interference with the resident’s ability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

• As a result of the failure of the facility’s system to assure that medications (including controlled substances) were stored in locked compartments, a resident removed and consumed a limited number of medication tablets; the resident required hospitalization to treat the resulting mental or physical outcomes (e.g., delirium, electrolyte imbalance, fracture, GI bleeding).

• Medication labeling was incomplete and lacked accessory instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in the inactivation of the medications and worsening of residents’ symptoms, ultimately necessitating hospitalizations.

• The facility failed to implement a system to reconcile controlled substances and when the residents for whom the medications were prescribed experienced moderate to severe pain that compromised the ability to perform ADLs, medications were unavailable.

NOTE: If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy
Level 2 indicates non-compliance that results in a resident outcome of no more than minimal discomfort and/or the potential to compromise the resident’s ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- The facility’s pharmaceutical storage system (medication cart) was not under direct observation of authorized staff during a medication pass and medications which pose minimal risk were on the top of the cart, thus permitting potential resident access to medications for a brief period.

- Staff, who were not authorized to have access to medications, stored lunches and personal belongings in the locked medication and treatment room and were able to access the medication room keys from a drawer at the nursing station. Subsequently, they had access to unlocked stock and emergency medications stored in the medication room.

- Labeling of the jar containing an ointment prepared by the pharmacy did not indicate the ingredients in the ointment potentially allowing the resident to develop discomfort or a minor skin reaction from known sensitivity to one of the ointment’s ingredients.

- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions more than monitoring.

**Severity Level 1 Considerations: No actual harm with potential for minimal harm**

Level 1 indicates non-compliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples of potential negative outcomes may include, but are not limited to:

- The facility failed to reconcile controlled medications for a period of 6 months but there was no negative resident outcome.