MEDICATION MANAGEMENT AND REDUCTION OF ADVERSE DRUG REACTIONS

Revised February 2004

CARE PROCESS STEP	EXPECTATION	RATIONALE
Assessment/Problem Recognition		
1. Was the problem or condition (onset, frequency, intensity, duration, etc.) for which a medication was being given clearly identified?	-When medication is prescribed in response to an identified problem or condition, the staff and health care practitioner should ensure that the problem has been clearly identified, or that there is some rationale for empirical interventions. -Symptoms should be characterized in sufficient detail (onset, nature, location, duration, progression, intensity, frequency, etc.) to help identify whether a problem exists that requires an intervention and the potential causes of the problem.	- Medications are often helpful in addressing problems of elderly individuals. - However, many medications can cause significant adverse drug reactions (ADRs); the risk of having a significant ADR increases as the number of medications increase. -Frail elderly and chronically ill individuals often exhibit symptoms as side effects of treatment. These symptoms may be mistaken for a new illness, leading to additional treatment, which can lead to further complications. -By suspecting and responding to a possible adverse drug reaction (ADR), facility staff and the physician can potentially reverse the symptoms and head off subsequent complications by a change in medications.
2. Was the rationale for the use of medication as treatment for the problem or condition clearly identified?	- There should be a clear indication for the use of each medication given to a resident, based on considering the resident's age, conditions, risk factors, and health status. -The rationale should clearly indicate why the resident is receiving the prescribed medication (what the medication is supposed to do or prevent) -In the case of a newly admitted resident, it may take time to obtain a history that justifies the use of a particular medication, but in the clinical judgment of the medical provider, the benefits of continuing to use the medication outweigh the potential risks to the resident. - For any medication with a significant risk of ADRs, if the indication is unclear, documentation	-A clearly identified rationale for treating a problem/condition with a prescribed medication helps demonstrate that the information collected during the comprehensive assessment was used to determine the most appropriate treatment. -The rationale guides the development of the individualized medication plan for the resident. -A diagnosis by itself may not suffice; just because a condition exists does not necessarily mean that it has to be treated, or that a medication is necessary.

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	should reflect the rationale for continued use during this time. -Medications prescribed without a clear rationale or on a PRN (as needed) basis should be carefully reviewed to make sure they are being given to treat a problematic condition or risk, instead of in response to a medication side effect mistaken for a new condition or a symptom of an untreated illness.	
3. Were risk factors identified for the use of prescribed medications, given the resident's condition and existing medication profile?	- The MDS and other relevant information should be reviewed to identify risk factors that are likely to predispose a resident to adverse drug reactions. -Whenever there is a significant change in the resident's condition, a reassessment should be completed. -Suspected adverse drug reactions should be identified and pursued. -The consultant pharmacist should conduct a more focused medication review for individuals with significant condition changes; especially, repeat falling, anorexia, and changes in mental status or behavior.	-Medications are often helpful to the elderly, but functional decline and serious adverse drug reactions can often be attributed to various medication combinations. -Identification of risk factors that are likely to predispose a resident to adverse drug reactions is a necessary part of medication management. Many ADRs are serious, even life-threatening. -Because the symptoms of an ADR often resemble those of an acute illness, the true cause of the problem may be overlooked unless doctors, nurses, and consultant pharmacists are aware of the possibility. -MDS data such as cognitive patterns, communication patterns, vision patterns, mood and behavior patterns, physical functioning and structural problems, continence, disease diagnosis, health conditions, nutritional status, oral/dental status, skin condition, activity pursuit patterns, medications, and special treatments and procedures is useful for identifying risk factors. - This information may help identify the need for closer monitoring, identify existing signs/symptoms that could be confused with ADRs, or identify the need to revise the current medication regimen to minimize medications that may exaggerate current symptoms. For example,

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		someone with a seizure disorder may be at risk from medications that lower the seizure threshold; a resident may be at increased risk for falls due to medication combinations that cause dizziness or postural hypotension.
Diagnosis/Cause Identification		
4. For any new or recurrent loss of appetite/weight, fall, or change in mental status/behavior, was the drug regimen reviewed to determine the possibility that one or more medications may have contributed to the change in condition or functional decline?	-Once a change in condition has been identified, the staff and practitioner need to investigate the cause. -The consultant pharmacist must review the regimen monthly and may need to assist with interim reviews where a resident's symptoms or condition change suggest a possible ADR. -Ongoing discussions among the consultant pharmacist, nurses and physician about each medication regimen, including medications recently started or changed, are expected. -Over time, documentation should reflect ongoing review of the effects of medication administered and consideration of whether unresolved risks or recurrent symptoms warrant continued use of a medication, especially those with substantial risks for a particular resident. -The physician should document, or discuss with a nurse who documents, that a medication with significant risk potential in an individual resident has been considered as a potential cause of any a) significant condition change; b)new onset of a significant problem/condition or worsening of an existing one; or c) an otherwise unexplained decline in function or cognition.	-Medications are often the first "dominoes" in a chain reaction that may result in potentially preventable illness, functional decline, or even death. The geriatrics approach is to prevent the chain reaction or to intervene early enough to forestall serious complications. -Three common symptoms in those with chronic illnesses and disabilities that often reflect an ADR are: 1) loss of appetite (anorexia) or unplanned weight loss; 2) new or repeat falling, and 3) change in mental status or behavior. Long-term care residents may experience other equally or more significant side effects as well, depending upon that resident's conditions and medication profile. -The consultant pharmacist is in a key position to identify and alert the nursing staff and physician to potential medication causes of resident symptoms. -An adverse drug reaction can happen unexpectedly or repeatedly at any time in any resident. The nurses and physician should not simply rely on the consultant pharmacist to perform medication reviews, provide notification of risks/events, and/or make recommendations. -Often, medications are administered for months or years, despite the resolution of temporary problems. Residents may improve or remain stable despite, not because of, taking certain medications.

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5. When a new or recurrent loss of appetite/weight, fall, or change in mental status/behavior resulted in adding another medication to treat the symptom, was it explained why the additional medication was the most appropriate treatment?	-When a resident has new or recurrent weight loss/anorexia, falling, or change in mental status or behavior without a readily identifiable cause, the treatment team should consider the possibility that current medications may be causing or contributing to the symptom before deciding to prescribe additional medications to address the symptoms. -If additional medication is prescribed, the physician and nursing staff should document the reason why additional medication was warranted despite the possibility that the symptom could be related to the existing medication regimen. -When root causes of symptoms are not sought or addressed, documentation should reflect the rationale for a decision to treat the symptom instead of seeking or managing the cause.	-Symptoms of ADRs may mimic other conditions, resulting in overlooking the true cause of the problem. -As the number of medications increases, so does the risk for a serious ADR. -Although it may seem urgent to treat a reported symptom, it may be more judicious to consider the cause(s) of symptoms and whether another approach might be more prudent. -When someone is receiving hospice or palliative care for a terminal condition, relief of pain or other symptoms may outweigh the side effects of medications or the relevance of seeking causes. -Adequate documentation of the rationale for medication use shows why it was necessary for appropriate treatment of a particular resident.
6. When a recent change of condition has occurred, was an adverse drug reaction or a problem related to medication administration (transcription error, illegible handwriting, adequate fluid for swallowing, taken with/without food, the amount of medication taken at one time, right resident, right medication, right dose, right time, right route, etc.) considered as a contributing factor to the resident's change in condition?	-All aspects of medication orders and their execution must be accurate. -The orders or prescription, and the subsequent transcription, must be accurate, complete, understandable, and legible. -Facility routines should ensure that medications are passed at proper times, using proper procedures, and that the resident's routines are considered. -The correct medication must be given to the right resident, in the correct dose, by the correct route, and at the right time. -The facility should provide, and the staff should use, relevant resources and current reference materials regarding medications, including proper administration, and their associated effects and risks.	- Adverse drug reactions may result from mistakes in ordering or administering medications. -Professionals should use relevant evidence and follow pertinent standards of professional practice, to be aware of and address medication-related risks and symptoms. - The Physician's Desk Reference (PDR) and other standard references list most of the important side effects and risks associated with specific medications. Other resources such as various AMDA Clinical Practice Guidelines and the OBRA Resident Assessment Protocols (RAPs) list medication classes likely to cause or increase the risk of various symptoms. -Proper medication administration requires following relevant procedures for the drug and its use, knowledge of the resident , and coordinating facility routines. Examples include: Some medications are to be taken on

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	-Those providing the care should appropriately question situations that could represent an ADR and report their valid concerns.	an empty stomach; others must be taken with food; certain medications must be administered at certain times of the day to maintain adequate blood levels or to reduce the risk of an adverse event; oral medications require the ability to swallow the pill and adequate fluid intake to swallow properly.
Treatment/Problem Management		
7. Were significant risks related to individual medications or medication combinations, identified and addressed for individual residents?	-It is expected that a rationale will be documented when the dose, duration, or frequency of a prescribed medication is greater than the manufacturer's recommendations or than recommended in a specific population, or the medication is considered high-risk compared to other available, relevant alternatives. -Unless otherwise indicated, the physician should start with the lowest dose possible or substitute lower risk for higher risk medications. -It is expected that the medication will be reevaluated periodically for continued necessity. -The consultant pharmacist should help identify high-risk medications for the population of the facility, as well as for individual residents. -When the consultant pharmacist reports findings and recommendations, the attending physician, Medical Director, and Director of Nursing should acknowledge them in a timely manner and take appropriate action based upon their knowledge of the individual resident's condition, prognosis, and wishes for treatment or treatment limitations.	-Although medication management is primarily a physician and nursing responsibility, effective use of the consultant pharmacist may help in planning and/or achieving treatment goals, monitoring the resident's progress, and educating/training staff. -Timely and appropriate responses to notification of potential problem situations can prevent an adverse event or lessen its consequences. - Prescribing medications is a medical function requiring prudent use of clinical judgment and demanding professional accountability. -Some medications are prescribed for temporary conditions or the resident's status may change, rendering a medication unnecessary or risky. -Determination of individual risks should also consider food-drug interactions, effects of medication combinations, and drug-disease/condition implications.
8. Was it explained why the benefit of a high-risk medication, dose, medication combination or	-The physician and staff are expected to identify the rationale, goals and objectives of a resident's medication plan.	-Appropriate goals depend on understanding the nature and causes of an individual's condition/status and realistic potential treatments/interventions.

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other factors outweighed the potential risk?	-For high-risk medications, the physician or staff who have consulted with the physician should explain why treatment benefits were believed to outweigh the risks to the resident. -When a medication is prescribed to address problematic behavior, the facility must demonstrate that the medication is used to treat medical or neuropsychiatric symptoms, signs, or conditions. The goals and objectives must be clearly indicated. Response to treatment must be documented, including attempts to reduce the dosage and the response to this intervention. If dose reduction is not possible, or is clinically contraindicated, a relevant explanation must be provided.	-Having a pertinent rationale demonstrates that the staff used a systematic, evidence-based approach to analyze resident information and to create and implement a plan that is relevant to those needs. -Because of their risk of causing ADRs, medications prescribed for problematic behaviors should be used for specific indications, at the lowest effective dose, and for the shortest possible period of time. A process to monitor and document behavioral responses to medication interventions is required to support treatment decisions. When using psychoactive medications, staff must document monitoring for tardive dyskinesia, postural hypotension, akathisia, and parkinsonism.
9. Were likely adverse drug reactions of loss of appetite/weight, falls, or change in mental status/behavior managed in a timely manner by changing the medication or dose, or documenting why such changes could not or should not be made?	-Probable ADRs should be addressed in a timely manner. - When a medication has been identified that may be associated with a probable adverse drug reaction, the medical practitioner should try to discontinue or taper dosage for a trial period to determine the effects, unless adjustment would create an immediate risk to life and health. -The rationale for the treatment decision should be clearly documented.	-ADRs may represent urgent or emergent conditions that require a timely response because of a threat to an individual's life, health, or safety. - Often, the only way to know if an ADR exists is to observe the results of stopping or adjusting the potentially problematic medication. - Being able to explain why a medication regimen was maintained or adjusted in response to a probable ADR, helps demonstrate a systematic approach to care based upon knowing the resident and the risks that medications pose.
Monitoring		
10. Was the resident periodically monitored for significant effects, side effects, and complications (monitor target symptoms, perform appropriate laboratory tests, etc.)?	-The facility must clearly demonstrate that it periodically reviews the indications and effects (desired and undesired) of each resident's medication regimen. -Utilizing current literature and recognized references, and relevant standards of professional	-A systematic approach including sufficiently detailed, relevant documentation helps the staff understand why medications are being given and how the resident is expected to benefit from them, what they are expected to do for the resident, so that they can identify the benefits and the complications of those interventions.

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	practice, staff should look for and report probable or suspected adverse drug reactions. -It is expected that the facility will have a reliable system for interpreting the significance of and reporting periodic diagnostic tests associated with medication monitoring. -The consultant pharmacist must review the medication regimen monthly, or more frequently if warranted. -The physician should review the relevance and possible problems of high-risk medications at least with each visit, and the overall regimen in more depth at least annually. - Periodically, the staff and practitioner should document the absence of significant ADRs in individuals taking medications associated with significant risks such as falling, change in mental status or level of consciousness, and unplanned weight loss/anorexia. -Periodically, the physician should review a resident's medication regimen with the staff, including the consultant pharmacist, for opportunities to reduce dosages or discontinue possible unneeded medications.	-Underlying causes of conditions may resolve, or the resident's status may change over time. Periodic monitoring is part of a systematic approach to care. -Diagnostic and laboratory tests may help identify effectiveness of treatment and may indicate untoward effects. -Because nursing staff provides daily care to the resident, they may be the first to observe symptoms and condition changes that could indicate a developing problem. -The consultant pharmacist reviews the medication regimen at least monthly, but may need to do a more frequent review related to the use of high-risk medications, including identification of factors such as comorbidities and medication combinations that could potentially affect the outcomes of drug treatment. -A safe, effective medication management system must contain accurate, current resident medication profiles at all times.
11. Was there a timely response to identified or likely adverse drug reactions?	-It is expected that the facility will use a reliable, consistent approach to identify and respond to ADRs in a timely manner. All direct care staff, physicians, and administrative staff should clearly understand their roles and responsibilities. -The medication management plan should contain criteria for determining the desired and undesired	-An effective medication management system requires all staff to understand and uphold their roles and responsibilities in identifying and responding to ADRs. Staff must understand what to report, when, and to whom, as well as what kind of a response they should be expecting from a practitioner. -The rationale for deciding whether to continue or to

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	effects of treatment, including significant or severe symptoms to be reported to the physician. -The physician should respond in a timely manner to reports of possible significant ADRs or other medication-related issues, relative to the urgency of the threat to an individual's life or health. -If the practitioner's response is to maintain the current medication regimen despite the probability of an ADR, documentation should explain why a change in treatment was not considered appropriate.	modify a current medication regimen in the presence of a probable ADR should show that the staff and practitioner systematically considered resident-specific information and other readily available information about potential medication complications, as is contained in the PDR and other references.
12. Was a possible adverse drug reaction monitored until the symptoms resolved or another cause for the symptoms was identified?	-When an adverse drug reaction is suspected, it is expected that the providers will follow up on the condition until the symptoms have resolved or another cause is identified. -Appropriate interventions should be made; for example, an individual experiencing delirium may need additional help with ADLs, or someone with medication-related anorexia may need additional support to get enough food and fluids.	-Sometimes symptoms will resolve spontaneously, but medications (either individually or in combination) may exacerbate symptoms or otherwise adversely affect resident status/function, especially in combination with other drugs. -It may not be prudent to prescribe another drug to treat a symptom, as this may add to the drug regimen without treating the root cause of the problem, and may increase the potential for additional ADRs. - ADRs often affect an individual's function and cognition, resulting in the need for additional support until the symptoms resolve.