
Consultant Pharmacy Law Update

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Objectives

- ◆ Discuss current issues related to consultant pharmacy practice
- ◆ List recognized clinical resources available to the consultant pharmacist
- ◆ Discuss monitoring medications and tracking progress towards the therapeutic goals of the patient
- ◆ Review medications listed in Table I of tag F329
- ◆ Review anticholinergic medications listed in Table II of tag F329

Current Issues In Long-Term Care

- ◆ **DEA Enforcement Actions Against Long-Term Care Pharmacies.** May 2009 DEA agents have conducted inspections in several LTC pharmacies in Ohio. The focus of these inspections include:
 - Dispensing CII, III, IV, and V medications based upon a chart order faxed by the facility to the pharmacy. DEA does not consider a chart order to meet the legal requirements of a valid prescription under 42 CFR 1306.21.
 - DEA does not recognize the LTC nurse as the agent of the prescriber
 - Dispensing CIII, IV, & V meds upon the oral orders of the LTC nurse after the nurse has received the order from the physician
 - Using the exception for emergency orders for non-emergencies, including situations where the need for the drug could have been anticipated by the prescriber/pharmacy
 - Medications dispensed from an emergency box without a valid prescription.

Current Issues In Long-Term Care

- ◆ FDA acts to halt marketing of certain unapproved prescription narcotics (March 30, 2009).
- ◆ FDA warned 9 companies to stop manufacturing 14 unapproved narcotic drugs that are marketed in several dosage forms and are widely used to treat pain including:
 - High concentrate morphine sulfate oral solution
 - Morphine sulfate immediate release tablets
 - Hydromorphone immediate release tablets
 - Oxycodone immediate release tablets (capsules not affected)
- ◆ FDA reversed its decision for high concentrate morphine sulfate oral solution 20 mg/mL on April 9, 2009 on an interim basis
 - FDA will allow manufacturing on an interim basis until an FDA approved or alternative therapy is available

Current Issues In Long-Term Care

- ◆ FDA Joint Advisory Committee on Acetaminophen June 29 – 30, 2009 made the following recommendations
 - Recommend that the max daily dose (4 gm/day) in nonprescription single ingredient and combination products be lowered (3,250 mg/day)
 - Max nonprescription single be limited to 650 mg
 - If the current maximum dose of acetaminophen recommend that the current maximum dose of acetaminophen (2 x 500 mg) be switched to prescription status
 - *Pack size limits be implemented for nonprescription products
 - *Eliminating nonprescription acetaminophen combination products
 - Only one concentration of nonprescription liquid be available
 - Eliminate prescription acetaminophen combination products
 - If prescription combination products continue to be marketed, recommend that “unit-of-use” packages be required
 - FDA require a boxed warning for prescription combination products.

Current Issues In Long-Term Care

- ◆ Florida enacts law mandating bulk medication be repackaged for nursing home residents
- ◆ Senate Bill 1280 requires any registered pharmacist under contract with a nursing home to repackage bulk medication, which has been packaged by another pharmacist licensed in any state in the U.S. into a unit dose system compatible with the system used by the nursing facility.
- ◆ A pharmacist who correctly repackages and relabels the medication under the provisions of this act shall not be held liable in any civil or administrative action arising from the repackaging
- ◆ Pharmacist who repackages and relabels prescription medications may charge a reasonable fee for costs

Resources

- ◆ American Medical Directors Association (AMDA)
www.amda.com
- ◆ American Society of Consultant Pharmacists (ASCP)
www.ascp.com
- ◆ Center for Medicare and Medicaid Services (CMS) formerly Health-Care Financing Administration (HCFA)
www.cms.hhs.gov
- ◆ American Geriatrics Society www.americangeriatrics.org
and www.geriatricsatyourfingertips.org
- ◆ Agency for Healthcare Research and Quality www.ahrq.gov

Resources

- ◆ Quality Improvement Organizations: www.medqic.org
- ◆ CMS Sharing Innovations in Quality:
www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp
- ◆ Association for Practitioners in Infection Control and Epidemiology: www.apic.org
- ◆ Society for Healthcare Epidemiologist of America, Long-Term Care Committee: www.shea-online.org
- ◆ U.S. Food and Drug Administration: www.fda.gov
- ◆ National Institute of Mental Health: www.nimh.nih.gov

Resources related to MRR

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

Clinical Resources for Pain Management

- ◆ American Geriatrics Society Clinical Practice Guideline
http://www.americangeriatrics.org/education/cp_index.shtml
- ◆ American Medical Directors Association Clinical Practice Guideline “Pain Management in the Long-Term Care Setting”
www.amda.com/tools/guidelines.cfm

F-Tag 309 – Pain Management

- ◆ Effective date – March 31, 2009
- ◆ Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care
- ◆ Key components include
 - Care process for pain management
 - Pain recognition
 - Assessment
 - Management of pain
 - Non-pharmacological interventions
 - Pharmacological interventions
 - Monitoring, reassessment and care plan revision

F-Tag 309 – Pain Management

- ◆ Surveyors will review any resident who
 - States he/she has pain or discomfort
 - Displays possible indicators of pain that cannot be readily attributed to another cause
 - Has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain
 - Assessment indicates that he/she experiences pain
 - Receives or has orders for treatment for pain
 - Has elected a hospice benefit for pain management

F-Tag 309 – Pain Management

- ◆ Consultant pharmacist is mentioned as a key member of the interdisciplinary team responsible for overseeing residents' pain management regimens
- ◆ Surveyors are directed to interview the consultant pharmacist if the interventions or care provided do not appear to be consistent with current standards of practice or the resident's pain appears to persist or recur
- ◆ Surveyors are supposed to determine whether medications ordered to treat pain are being monitored for effectiveness and for adverse consequences (F-tag 329)
- ◆ Surveyors are encouraged to evaluate other related F-tags, including F-tag 425 to determine if the medications were available and administered as indicated

Additions

- ◆ Tag F 315 – Urinary Incontinence
 - Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);
- ◆ Tag F 314 – Pressure Ulcers
 - Many studies and professional documents identify risk factors that increase a resident's susceptibility to develop or to not heal pressure ulcers.
 - Examples of these risk factors include, but are not limited to medications such as steroids that may affect wound healing

Additions

- ◆ F-Tag 325 – Nutrition Assessment
 - Medications and nutritional supplements (prescribed and over-the-counter) may affect, or be affected by, eating or the intake or utilization of nutrients (e.g., Warfarin/Vitamin K, liquid Dilantin/tube feedings, etc.). Medications from almost every drug category may affect nutritional status by causing or exacerbating lethargy, confusion, nausea, constipation, or anorexia.

Tag F334 - Vaccinations

- ◆ **Influenza – Facility must develop policies and procedures that**
 - Each resident or legal representative receives education regarding potential benefits/hazards and side effects
 - Resident is offered influenza Oct. 1 through March 31 annually unless clinically contraindicated
 - Resident has the right to refuse immunization
- ◆ **Pneumococcal**
 - Each resident or legal representative receives education regarding potential benefits/hazards and side effects
 - Resident is offered pneumococcal clinically contraindicated or resident has already received immunization.
 - Resident has the right to refuse immunization

Monitoring

- ◆ **A comprehensive care plan that reflects appropriate medication related goals and parameters for monitoring the resident's condition**
- ◆ **Optimize the therapeutic benefit of medication therapy and minimize or prevent potential adverse consequences**
- ◆ **Establish parameters for evaluating the ongoing need for the medication**
- ◆ **Verify or differentiate the underlying diagnoses or other underlying causes of signs or symptoms**

Monitoring

- ◆ **Sources of information defining monitoring criteria or parameters**
 - Manufacturers' package inserts and black-box warnings
 - Facility policies and procedures
 - Consultant pharmacists
 - Clinical practice guidelines or clinical standards of practice
 - Medication references
 - Clinical studies with evidence, evidence-based medicine, or studies published in medical and/or pharmacy journals

Monitoring

◆ Physiological, Cognitive, and Functional Status

- Vital signs
- Electrocardiograms and rhythm strips
- Blood glucose, Hemoglobin A1C
- Resident Assessment Instrument (RAI)
- Functional Alzheimer's Screening Test (FAST) scale
- Physical Self Maintenance Scale (PSMS)
- Pain
- Mini-Mental Status Exam (MMSE)
- Confusion Assessment Method (CAM)
- Instrumental Activities of Daily Living Scale (IADL)
- Abnormal Involuntary Movement Scale (AIMS)

Monitoring

◆ 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)
- Cohen-Mansfield Agitation Inventory (CMAI)
- Neuro-psychiatric Inventory-Nursing Home Version (NPI-NH)

Developing a Monitoring Plan

◆ Identifying the essential information and how it will be obtained

- Drug-drug, drug-food interactions
- Clinical condition
- Black-box warnings
- History of adverse consequences related to similar medication

◆ Determining the frequency of monitoring

- Periodic planned evaluation of progress toward the therapeutic goal
- Continued vigilance for adverse consequences
- Evaluation of identified adverse consequences

Developing a Monitoring Plan

- ◆ Defining the methods for communicating, analyzing, and acting upon relevant information
- ◆ Re-evaluating and updating the plan periodically
 - 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
 - Significant changes in diet that may affect medication absorption or effectiveness
 - Changes in manufacturers' specification, FDA warnings, pertinent clinical practice guidelines or other literature updates

Inadequate Monitoring

- ◆ 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. warfarin without monitoring PT/INR, amiodarone without monitoring cardiac, pulmonary, thyroid, and liver function)

Inadequate Monitoring

- ◆ 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
 - Inadequate or absent evaluation, including PT/INR during treatment
 - Failure to recognize and monitor the increased risk when the resident is receiving other medications (e.g. digoxin, amiodarone, antibiotics, fluconazole, etc.) that are known to interact with warfarin and increase the PT/INR
 - Failure to act when the PT/INR exceeds the target goal

OSCAR Data – February 2009

Region	Psycho-tropic	Anti-psychotic	Anti-depressant	Anti-anxiety	Sedative-Hypnotic
USA	64.9%	25.5%	47.7%	19.2%	7.2%
MS	67.6%	29.7%	50.4%	18.4%	9.7%
AL	68.7%	26.8%	52.4%	23.2%	7.0%
TN	73.7%	30.8%	57.8%	26.4%	10.3%
LA	68.5%	33.0%	48.7%	19.2%	11.6%
AR	66.1%	28.2%	48.7%	18.2%	5.5%
FL	65.9%	26.8%	47.6%	24.8%	12.5%

Trends in Nursing Home Deficiencies and Complaints

- ◆ In each of the past 3 years, over 91 % of nursing homes surveyed were cited for deficiencies.
- ◆ Almost 17% of nursing homes surveyed were cited for actual harm or immediate jeopardy deficiencies in 2007
- ◆ In the past 3 years. The average number of deficiencies per nursing home increased slightly
 - 2005 average deficiencies per nursing home = 6.4
 - 2006 average deficiencies per nursing home = 6.9
 - 2007 average deficiencies per nursing home = 7.0
- ◆ The most common deficiency categories cited in each of the past 3 years were
 - Quality of care
 - Resident assessment
 - Quality of life

% Nursing Homes Surveyed With Deficiencies by State 2005-2007

State	2005	2006	2007
Mississippi	86.6%	87.1%	86.7%
Alabama	97.6%	97.0%	96.8%
Tennessee	95.5%	91.1%	92.0%
Louisiana	92.5%	91.8%	94.7%
Arkansas	95.4%	97.6%	97.9%
Florida	97.1%	96.8%	97.2%

Average Number of Deficiencies/Nursing Home Surveyed by State 2005 - 2007

State	2005	2006	2007
Mississippi	3.7	4.0	4.3
Alabama	7.2	6.8	6.4
Tennessee	6.6	5.9	5.7
Louisiana	8.2	7.1	7.9
Arkansas	9.3	10.7	8.6
Florida	7.5	8.3	8.0

% of Nursing Homes Surveyed That Received at Least One Deficiency by Category 2005 -2007

Deficiency Category	2005	2006	2007	% Point Difference 2005-2007
Quality of Care	70.6	71.5	73.6	3.1
Resident Assessment	54.4	58.0	58.2	3.8
Quality of Life	43.1	45.6	43.3	0.2

% Nursing Homes Surveyed Receiving at Least One Deficiency for Quality of Life 2005-2007

Deficiency Category	2005	2006	2007	% Point Difference 2005 - 2007
Dietary Services	43.1	44.4	42.9	-0.2
Resident Rights	33.4	34.5	34.3	0.9
Administrative Services	28.9	31.5	30.7	1.9
Pharmacy Services	23.8	25.3	28.8	5.0
Infection Control	26.3	28.7	28.4	2.4
Resident Behavior & Facility Practices	26.4	26.7	27.4	1.0
Physical Environment	22.9	23.7	23.8	0.9
Lab & Radiology	6.9	7.9	9.1	2.2
Nursing Services	4.2	5.3	6.9	2.7
Physician Services	4.6	5.4	5.7	1.1
Admission/Transfer/Discharge	1.6	1.6	1.7	0.1
Rehabilitative Services	1.3	1.5	1.4	0.2
Dental Services	1.2	1.4	1.4	0.2

Table I

- ◆ Table I lists examples of some categories of medications that are likely to cause clinically significant adverse consequences in the elderly
- ◆ Table I is not all inclusive and does not address all issues related to medication use, such as dosages
- ◆ Medications other than those listed in Table I may present significant issues related to indications, dosage, duration, monitoring, or potential for clinically significant adverse consequences. Recommended to consult an authoritative source

Table II

Medications with significant anticholinergic properties

- ◆ Antihistamines
- ◆ Respiratory (ipatropium, tiotropium)
- ◆ GI Antispasmodics
- ◆ Antidepressants – Tricyclic and SSRI (trazodone)
- ◆ Muscle relaxants
- ◆ Phenothiazine antiemetics
- ◆ Urinary Incontinence Medications
- ◆ Antiparkinson medications (Anticholinergic)
- ◆ Antipsychotic medications
- ◆ Antivertigo medications

Adverse Consequences of Anticholinergic Medications

- ◆ Slowed passage of food through the GI tract
- ◆ Constipation
- ◆ Decreased sweating
- ◆ Dry mouth, nose, skin
- ◆ Elevated BP
- ◆ Bloating
- ◆ Blurred vision
- ◆ Cognitive decline
- ◆ Drowsiness
- ◆ Difficult urination/Urinary retention
- ◆ Difficulty swallowing
- ◆ Headache
- ◆ Impaired attention
- ◆ Increased sensitivity to light
- ◆ Nausea/vomiting
- ◆ Unusual tiredness/weakness

Serious Signs of Accumulation

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

Case

DS is an 82 y/o female recently admitted to the nursing home
Allergies: NKDA Weight 99 lbs. Height 4'9"
Recently admitted to the nursing home after a fall at her home. Daughter notes that her mother has been in declining health over the last year. She states that "Mom has little appetite, anemia, weakness, tiredness, and dizziness."

PMH: Anxiety, CHF, and Coronary Heart Disease, Depression, Osteoporosis

Current Medications:

FeSO ₄ 325 mg tid	omeprazole 20 mg qday
calcium 500 mg + Vit D bid	calcitonin nasal spray qday
furosemide 40 mg qday	ASA 81 mg qday
KCl 10 mEq qday	metolazone 2.5 mg qday prn
olanzapine 2.5 mg q5pm	bupropion XL 150 mg qday
lisinopril 10 mg qday	docusate sodium 200 mg bid
ipratropium nasal spray	digoxin 0.125 mg qday
	megestrol 625 mg qday

Case

Complaints began 3 – 4 months ago after starting several new medications including calcitonin, olanzapine, and omeprazole.

There has been a 5 pound weight loss over the past 2 months
BP 168/74 Pulse 68 Resp 20 Temp 98.6°F
EtOH – None Tobacco - None

Labs:

Na – 144 (135 – 147)	K – 3.4 (3.4 – 5.0)	Cl -102 (95-102)
CO ₂ – 28 (22 – 28)	BUN – 28 (5 – 20)	Cr – 1.2 (0.5 – 1.5)
Glucose – 98 (70 – 100)	Ca – 9.1 (8.6 – 10.3)	Dig – 0.5 (0.8 – 2.0)

ROS – reveals difficulty swallowing, taste disturbance, dry mouth, drowsiness, rhinitis, vision difficulties, and constipation.

Case – Medication Problems

- ◆ Constipation – olanzapine, iron, calcium
- ◆ Swallowing problem – dry mouth can be caused by furosemide, metolazone, olanzapine, ipratropium
- ◆ Heart failure – needs to increase lisinopril, consider metoprolol XL and spironolactone therapy
- ◆ Dehydration/hypokalemia – consider d/c metolazone (unless persistent fluid retention). Increase potassium dose, check serum magnesium
- ◆ Indication for olanzapine is not clear
- ◆ Taste disturbance/rhinitis – ipratropium, calcitonin
- ◆ Use of 2 psychotropic medications increase risk for falls
- ◆ May need to address CHD (if angina is present)
- ◆ May need to change bupropion (increased adverse effects including agitation, nausea, insomnia, anxiety, and blurred vision)
- ◆ Megesterol may be ineffective for weight gain in the elderly and is associated with increased incidence of mortality in nursing home patients

Med Pass Procedure

- ◆ Observe different routes and/or forms of medications (IV, IM, SQ, Transdermal, Inhaler, eye drops, Enteral tubes)
- ◆ Observe the administration of at least 20 – 25 medications observing as many staff administering medications as possible to facilitate a review of the facility’s entire medication distribution system
- ◆ Record from the medication label the name and dose/concentration of each medication administered, the route of administration and the expiration date (if expired)
- ◆ Record all multiples (2 drops, 2 tablets). For liquids, record actual volume or “rounded teaspoonfuls” and the amount of liquid

Med Pass Procedure

- ◆ Observe whether the staff confirmed the resident’s identity prior to giving medications and whether the medications were identified up to the point of administration
- ◆ Record the techniques and procedures that staff used to handle and administer medications (proper hand hygiene, checking pulses, flushing G-tubes, crushing medications, route/location of administration, shaking or rotating medication, giving with or between food or meals)
- ◆ Observe whether the staff immediately documented the administration/refusal of medication after the administration or attempt.

Medication Storage

- ◆ Medications are accessible only to authorized staff and are locked when not under the direct observation of authorized staff
- ◆ Controlled medications are stored in a manner to limit access and facilitate reconciliation in accordance with the facility policies

Medication Storage

- ◆ Medications are stored to maintain their integrity and to support safe administration of the correct medication, to the correct resident, by the correct route, and in the correct dose such as
 - Temperature, light, and humidity controls meet specifications for the medication
 - Medications available for use are not expired, contaminated, or unusable
 - Medication labels are legible; intact; contain the name and dose/concentration of the medication, appropriate accessory instructions, expiration date when applicable; and support the safe administration of the medication
 - Multi-dose vials are labeled per facility policy and manufacturer's specifications once use of the vial has been initiated

Controlled Substances

- ◆ Schedule II medications must be maintained in separately locked permanently affixed compartments
- ◆ Access system used to lock Schedule II medications and other meds of abuse cannot be the same access system used to obtain non-scheduled medications.
- ◆ Facility must have a system to limit who has security access and when access is used
- ◆ EXCEPTION – Controlled medications and those subject to abuse may be stored with non-controlled medications as part of a single-unit package medication distribution system, if the supply of medication(s) is minimal and a shortage is readily detectable.

Controlled Substances

◆ **Facility should have a system to account for the receipt and disposition of all controlled substances including, but not limited to**

- Record of receipt of all controlled medications specifying the name/strength of medication, quantity received, and name of the resident or the emergency medication supply.
 - » Note that the facility may store some controlled medications in an emergency medication supply in accordance with state requirements. Facility's P & P must address reconciliation and monitoring of this supply.
- Documentation of usage (MAR, Proof-of-use sheets, declining inventory sheets)
- Documentation of disposition including destruction, wastage, return to the pharmacy/manufacture, or disposal in accordance with state law
- Periodic reconciliation of the records (at least monthly or more frequently as defined by the facility)
