1-17-07

To: PHARM 492 Students

From: Joy B. Plein, PhD, CGP, FASCP

Re: preparation for PHARM 492 workshop on 1-23-07

Introduction to readings for the PHARM 492 discussion and workshop on Federal and State Regulations affecting pharmacy practice in nursing facilities and assisted-living facilities.

Attached are notes that will serve as part of your reading assignment and as your handout for the January 23 discussion and workshop in Regulations on LTC. I hope the size of these notes will not seem formidable or intimidating and that you will at least print and scan the document before class and that you will read the assigned article (Martin CM, McSpadden CS. Changes in the state operations manual: implications for consultant pharmacy. Consul Pharm 206: 948-950,953-961). Access to the assigned article is on the PHARM 492 website.

In class, we will "walk through" the handout and then you will work in assigned groups to apply the information by answering clinical and administrative questions related to LTC pharmacy practice in nursing facilities (NFs), assisted-living facilities (ALFs), adult family homes and independent-living seniors. I think that by applying the regulations you will find that the information is not overwhelming and is interesting as well important. The handout contains excerpts of the Federal regulations and the latest "interpretive guidelines" (became effective 12-18-06) are standards for pharmacist's responsibilities to NF patients. Although Federally mandated only for NF practice, the guidelines are appropriate standards for pharmacist's practice and accountability in all practice sites. For convenience in our brief review of the Washington state WAC on pharmaceutical services for extended care facilities, the handout also includes the WAC. I will call your attention to a few parts of this document and we will also briefly discuss the other regulations in the handout.

For January 23, you will need to bring the handout and you will probably also want To bring a high lighter.

I think you will find it interesting to go to http://www.medicare.gov and go to "nursing home compare" to see what information is available on line including the surveyors reports from their latest "survey".

I look forward to working with you on January 23!

492 regs '07 to students
JBP: 1-17-07

PHARM 492. Handout for Workshop on Laws, Regulations & Guidelines "Governing" Pharmacy Services for LTC

Joy B. Plein, PhD, RPh, CGP, Professor of Pharmacy

Nursing Facilities (Federal Regulations)

1. A historical perspective of the dynamic process

   - Prior to 1965 there were regulations only at the State level

   - With the enactment of Medicare and Medicaid in 1965, the Federal government developed "conditions" (requirements for funding) and "standards" (lesser requirements) in order for a facility to be funded under these programs. Pharmacists responsibilities were mainly "accountability and storage" of medications.

   - In 1974, a revision of the Federal regulations mandated pharmacist-conducted drug regimen review (DRR) and also increased pharmacists participation and responsibility in other aspects of medication use in nursing homes. *This regulation is historic because it mandated clinical pharmacy*. There were separate regulations for SNFs (skilled nursing facilities, ICFs (intermediate care facilities), and ICF/MRs (intermediate care facilities for the mentally retarded). For SNF residents, regulations required that each resident's medication regimen be reviewed by a pharmacist at least once each month and the SNF was required to have a pharmaceutical services committee that met at least once every three months was mandated.

   - In 1982, the Government Accounting Office reported that the results of DRR were falling short of expectations and HCFA responded by issuing "the indicators" (revised in 1985) to help the "surveyors" (nursing home inspectors) evaluate the pharmacist's clinical services. Some parts of the "indicators" were carried over into the "interpretive guidelines" which are used by CMS surveyors in their evaluations of the quality of services, including pharmacists' clinical and managerial services to SNFs and their residents.

- In 1987, Congress enacted OBRA '87 (10-16-87) which revised the 1974 Nursing facility regulations that were published in 1989 and became effective, along with interpretive guidelines, on 10-1-90. A revision was published as final regulations 9-26-91 and became effective 4-1-92. (OBRA is the acronym for Omnibus Budget Reconciliation Act). OBRA included regulations that :

    - Insure patient privacy
    - Insure appropriate use of restraints including psychotropic drugs
    - Require comprehensive resident assessments
    - Combine regulations for SNFs and ICFs into one set of regulations
    - Increase emphasis on DRR by pharmacists
    - Comprehensive care plans
    - Emphasis on appropriate use of antipsychotic medications

- CMS (formerly HCFA) updates the regulations in Medicare and Medicaid Requirements by changing and/or adding to the "Interpretive Guidelines" issued to surveyors. Substantial changes were made in July 1999 by adding additional guidelines to the section of "quality of care" (483.25 part l. Unnecessary Drugs), and "drug regimen review (483.60 part c drug regimen review) sections, by citing potential problems in use of certain drugs in older patients or use of certain drugs with certain diagnoses. The drugs specified in that addition to the Guidelines are known as "Beers' drugs because they were identified in a consensus panel study as reported by: *Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. Arch Intern Med. 1997;157:1531-1536.* In the 12-18-06 update to the State Operations Manual (see below), the sections of the Interpretive Guidelines that cited Beers' drugs and guidelines for use of antipsychotics and sedatives/hypnotics were replaced by very comprehensive guidelines for surveyors to use in evaluating compliance with the 483.25(l) Unnecessary Drugs section of the Regulations.

- On December 15, 2006, CMS issued revisions, effective December 18, 2006 to the State Operations Manual (SOM), the document that instructs surveyors on conducting evaluations of, and standards for, SNFs, including clinical pharmacy consultant, dispensing, and medication provision services. The updates to "unnecessary medications" (new Tag F329) and "pharmaceutical services" (new Tags F425, F428, F431) are in Appendixes P and PP of the SOM. (The term Tag and a number is an identifier to the surveyor of the location of subjects in the SOM.)

2.1 A partial index to the Federal Regulation on nursing facilities that includes the sections of particular importance to pharmacists:

483.10 Residents rights
(n) self-administration of drugs

483.20 Resident assessment
(b) comprehensive assessment
(c) accuracy of assessments
(d) comprehensive care plan

483.25 Quality of care
(l) unnecessary drug
(m) medication errors

483.30 Nursing Services

483.40 Physician services

483.60 Pharmacy Services

483.75 Administration

2.2 Following are two of the most important regulations (bolded) for pharmacy practice in SNFs.

483.25(l) Unnecessary Drugs

(1) General. Each resident's drug regimen must be free from unnecessary drugs.

An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced; or
(vi) Any combinations of the reasons above.

(2) Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to

treat a condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

483.25 (m) Medication Errors—The facility must ensure that—

(1) It is free of medication error rates of five percent or greater; and

(2) **Residents are free of any significant medication errors.**

483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation

(c) Drug regimen review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing and these reports must be acted upon.

(d) Labeling of drugs and biologicals

(e) Storage of drugs and biologicals

The regulation itself includes additional text under parts b,d and e. Table 3 of the assigned article for PHARM 492, *Martin CM, McSpadden CS. Changes in the state operations manual:Implications for consultant pharmacy practice. Consult Pharm. 2006;21:948-950,953-96,* provides an excellent description of the many administrative, consultative, and service coordinating responsibilities required of consultant pharmacists for SNFs.

Pharmacists' responsibilities described in the Interpretive Guidelines may be grouped into two major categories—(1) clinical care and (2) management and coordination of medication services.

1. Pharmacist's clinical care

Medication Regimen Review. The Guidelines define medication regimen Review (MRR), which in this revision of the SOM is the term used instead of drug regimen review (DRR) as "a thorough evaluation of the medication regimen

by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team". As noted in the regulation the pharmacist's recommendations as documented in the DRR "must be acted upon", the new Interpretive Guidelines require that if the attending physician does not agree with the pharmacist's recommendations, that he/she must document the reason for refusal. The pharmacist's MRR report is "considered part of each resident's clinical record" and if documentation of the findings is not in the active record, "it is maintained within the facility and is readily available for review".The new Guidelines also require that MRR be conducted for short-stay residents.

- The new Guidelines say that the attending physician plays a key leadership role in medication management by developing, monitoring, and modifying the medication regimen in conjunction with residents and/or representative(s) and other professionals and direct care staff (the interdisciplinary team) and they say further that "***When selecting medications and non-pharmacological interventions, members of the interdisciplinary team participate*** in the care process to identify, assess, address, advocate for, monitor, and communicate the resident's needs and changes in condition."

- The Guidelines require that ***monitoring for efficacy and adverse consequences*** of medications be incorporated into the resident's care plans and that the "resident's clinical record documents and communicates to the entire team the basic elements of the care process." The Guidelines include a table of tools (laboratory and functional tests) that pharmacists will find useful in planning some of their recommendations for monitoring of residents' baseline and treatment status.

- The Guidelines require ***periodic specified gradual dose reduction (GDR)*** of antipsychotic drugs, sedatives/hypnotics, or anticonvulsants or antidepressants, if these latter drugs are being used to manage behavior, stabilize mood or treat a psychiatric disorder. The frequency of GDR is specified as are the rationales and documentation needed to show why GDR may be contraindicated. A GDR is required based upon the clinical indication for the drug for a specific resident rather than upon its pharmacologic classification.

- Whereas in the previous Interpretive Guidelines there was some emphasis on assuring safe use of psychopharmacologic medications, the current Guidelines are much more comprehensive and include a 39-page table listing pharmacologic/ therapeutic classes of drugs and individual drugs along with their issues and concerns in clinical use and daily dose "thresholds" for antipsychotics and anxiolytics.

2. Pharmacist's management and coordination of medication services

The pharmacist:

- is responsible for evaluating and coordinating all aspects of pharmaceutical services provided to all residents by all providers. Providing these services is prospective, concurrent and retrospective.
- provides routine and emergency medications.
- collaborates with the facility and medical director to develop IV therapy procedures if used within the facility, to determine the contents of the emergency kit, to develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services, establishing procedures for conducting, documenting and reporting the results of the MRR, and for addressing the irregularities.
- determines and monitors appropriate labeling and storage of medications.
- establishes records of receipt and disposition of controlled drugs and determines that records are in order and the account is periodically reconciled.

If you would like to access the 611-page interpretive guideline document which went into effect on 12-18, 2006, the online address is:

http://www.cms.hhs.gov/transmittals/downloads/R22SOMA.pdf

Explanatory Notes on Interpretative Guidelines for LTC M/M Regs

483.2 Resident Assessment, part (b) comprehensive assessment

RAI = MDS + triggers + RAPs -----→ comprehensive assessment

RAI = Resident Assesment Instrument
MDS = Minimum Data Set
triggers = specific respnses for MDS items that identify residents at risk for specific problems
RAP = Resident Assessment Protocol

TABLE 1. MDS SECTIONS

Section A.	Identification and Background Information
Section B.	Cognitive Patterns
Section C.	Communication/Hearing Patterns
Section D.	Vision Patterns
Section E.	Mood and Behavior Patterns
Section F.	Psychosocial Well-Being
Section G.	Physical Functioning and Structural Problems
Section H.	Continence in Last 14 Days
ction I.	Disease Diagnoses
Section J.	Health Conditions
Section K.	Oral/Nutritional Status
Section L.	Oral/Dental Status
Section M.	Skin Condition
Section N.	Activity Pursuit Patterns
Section O.	Medications
Section P.	Special Treatments and Procedures
ction Q.	Discharge Potential and Overall Status
Section R.	Assessment Information
Section T.	Therapy Supplement for Medicare PPS

TABLE 2. RESIDENT ASSESSMENT PROTOCOLS

RAP No.	RAP Title
1	Delirium
2	Cognitive Loss
3	Visual Function
4	Communication
5	ADL Functional/ Rehabilitation Potential
6	Urinary Incontinence and Indwelling Catheter
7	Psychosocial Well-being
8	Mood State
9	Behavior Problem
10	Activities
11	Falls
12	Nutritional Status
13	Feeding Tubes
14	Dehydration/Fluid Maintenance
15	Dental Care
16	Pressure Ulcers
17	Psychotropic Drug Use
18	Physical Restraints

Tables above are from Tobias DE, Feinberg JL, Troutman WG. MDS-Med Guide. Consultant Pharmacist. 1999; 14:831-834, 839-843, 847-850,852-854,857-860.

The MDS is important because it is:

1. the basis for PPS (prospective payment system)
2. the basis for case-mix for Medicaid reimbursement
3. used by surveyors to target the survey process in a NF
4. the basis for measuring the quality of a NF according to HCFA-established quality indicators (24 indicators with 3 "sentinel indicators"

Some Alphabet-Soup Abbreviations

AARP	American Association of Retired Persons
ADL	activities of daily living
CMS	Centers for Medicare and Medicaid Services
COLA	cost of living adjustment
CCRC	continuing care retirement community
DHHS	Dept of Health & Human Services (Federal)
DRGs	diagnosis-related groups
DRR	drug regimen review
DSHS	Dept of Social & Health Services (WA State)
DUE	drug use evaluation
DUR	drug utilization review
ECF	extended care facility
HCFA	Health Care Financing Administration
HIPPA	Health Insurance Portability & Accounting Act of 1996
IADL	instrumental activities of daily living
ICF	intermediate care facility
ICF/MR	intermediate care facility for the mentally retarded
LTCF	long term care facility/skilled nursing facility
MA	Medicare Advantage (program under part C of the Medicare Act)
MDS	minimum data set used in NFs
MMA	Medicare Modernization Act
NF	nursing facility
OSCAR	online survey certification & reporting system
PDP	prescription drug plan
PPO	preferred provide organization
PPS	prospective pricing system
POS	point of service

PSO	provider-sponsored organization
RUGs	resource utilization groups
SNFs	skilled nursing facilities

Nursing Facilities --State of Washington Regulations for Extended Care Facilities (State of Washington WAC 246-865)

For convenience the State of Washington WAC on pharmaceutical services for long-term care facilities is included in the handout. Please scan the sections identified below, and if there is time during our workshop, I will highlight some of it for you.

WAC 246-865-030 Emergency kit

WAC 246-865-040 Supplemental dose kits

WAC 246-865-060 Pharmaceutical services

1. administration
2. responsibilities of staff or consultant pharmacist
3. storage of drugs
4. labeling of drugs
5. control and accountability
6. controlled substances
7. drug administration

WAC 246-863-110 Monitoring of drug therapy by pharmacists

Chapter 246-865 WAC

Last Update: 1/5/94

Pharmaceutical services — extended care facility

WAC Sections

246-865-010
Definitions.

(1) "Board" means the Washington state board of pharmacy.

(2) "Department" means the state department of social and health services.

(3) "Dose" means the amount of drug to be administered at one time.

(4) "Drug facility" means a room or area designed and equipped for drug storage and the preparation of drugs for administration.

(5) "Legend drug" means a drug bearing the legend, "Caution, federal law prohibits dispensing without a prescription."

(6) "Licensed nurse" means either a registered nurse or a licensed practical nurse.

(7) "Licensed practical nurse" means a person duly licensed under the provisions of the licensed practical nurse act of the state of Washington, chapter 18.78 RCW.

(8) "Nursing home" means any home, place or institution licensed as a nursing home under chapter 18.51 RCW.

(9) "Pharmaceutical services committee" means a committee which develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice. The pharmaceutical services committee shall consist of a staff or consultant pharmacist, a physician, the director of nursing or his/her designee and the administer or his/her designee.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy under the provisions of chapter 18.64 RCW.

(11) "Pharmacy" means a place where the practice of pharmacy is conducted, properly licensed under the provisions of chapter 18.64 RCW by the Washington state board of pharmacy.

(12) "Practitioner" means a physician under chapter 18.71 RCW; and osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW; a dentist under chapter 18.32 RCW; a podiatrist under chapter 18.22 RCW; an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the committee of osteopathic commissioners; a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners; a registered nurse when authorized by the board of nursing under chapter 18.88 RCW, or a pharmacist under chapter 18.64 RCW.

(13) "Registered nurse" means a person duly licensed under the provisions of the law regulating the practice of registered nursing in the state of Washington, chapter 18.88 RCW.

(14) "Unit-dose" means the ordered amount of a drug in an individually sealed package and in a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(15) "Unit-dose drug distribution system" means a system of drug dispensing and control that is characterized by the dispensing of the majority of drugs in unit doses, ready to administer form, and for most drugs, not more than a 48-hour supply of doses is available at the residential care unit at any time.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 87-18-066 (Order 207), § 360-13-045, filed 9/2/87. Statutory Authority: RCW 18.64.005(11). 81-06-077 (Order 158), § 360-13-045, filed 3/4/81; Order 121, § 360-13-045, filed 8/8/74.]

246-865-020
Promulgation.

In the interests of protecting public health the Washington state board of pharmacy shall hereby allow the use of an emergency drug kit in any nursing home holding a valid Washington state nursing home license. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of the supplying pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-10-027 (Order 159), § 360-13-010, filed 4/28/81; Order 104, § 360-13-010, filed 12/5/69; Order 50 (part), filed 3/28/67.]

246-865-030
Emergency kit.

(1) The contents and quantity of drugs and supplies in the emergency kit shall be determined by the pharmaceutical services committee as defined in WAC 246-865-010(9) which shall consider the number of residents to be served and their potential need for emergency medications.

(2) A copy of the approved list of contents shall be conspicuously posted on or near the kit.

(3) The emergency kit shall be used only for bonafide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(4) Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the nursing home and the supplying pharmacy.

(5) The pharmaceutical services committee shall be responsible for ensuring proper storage, security and accountability of the emergency kit

(a) The emergency kit shall be stored in a locked area or be locked itself;

(b) Emergency kit drugs shall be accessible only to licensed nurses as defined in WAC 246-865-010(6).

(6) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to representatives of the board of pharmacy and the department.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-865-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-06-077 (Order 158), § 360-13-020, filed 3/4/81; Order 104, § 360-13-020, filed 12/5/69; Order 50, subsection 1-12, filed 3/28/67.]

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246-865-040
Supplemental dose kits.

(1) In addition to an emergency kit, each institution holding a valid Washington state nursing home license, and which employs a unit dose drug distribution system, may maintain a supplemental dose kit for supplemental nonemergency drug therapy if the necessary drug is not available from the pharmacy in a timely manner.

(2) The pharmaceutical services committee shall determine the quantities of drugs in the supplemental dose kit in light of the number of residents in the facility and their potential needs for supplemental doses.

(3) The supplemental dose kit shall remain the property of the supplying pharmacy.

(4) The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-06-077 (Order 158), § 360-13-030, filed 3/4/81; Order 114, § 360-13-030, filed 6/28/73.]

246-865-050
Drug facilities.

(1) There shall be facilities for drug preparation and storage near the nurses' station on each unit.

(2) The drug facilities shall be well illuminated, ventilated and equipped with a work counter, sink with hot and cold running water and drug storage units.

(3) The drug storage units shall provide:

(a) Locked storage for all drugs,

(b) Separately keyed storage for Schedule II and III controlled substances,

(c) Segregated storage of different resident's drugs.

(4) There shall be a refrigerator for storage of thermolabile drugs in the drug facility.

(5) Locks and keys, for drug facilities shall be different from other locks and keys within the nursing home.

(6) Poisons and other nonmedicinal chemical agents in containers bearing a warning label shall be stored in separate locked storage apart from drugs used for medicinal purposes.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). 81-06-077 (Order 158), § 360-13-055, filed 3/4/81; Order 121, § 360-13-055, filed 8/8/74.]

246-865-060
Pharmaceutical services.

(1) Administration of pharmaceutical services.

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(a) There shall be provision for timely delivery of drugs and biologicals from a pharmacy so a practitioner's orders for drug therapy can be implemented without undue delay.

(b) Unless the nursing home operates a licensed pharmacy and employs a director of pharmaceutical services, the nursing home shall have a written agreement with one or more licensed pharmacists who provide for pharmaceutical consultant services. The staff pharmacist or consultant pharmacist supervises the entire spectrum of pharmaceutical services in the nursing home.

(c) There shall be a pharmaceutical services committee whose membership includes at least a staff or consultant pharmacist, a physician, the director of nursing or his/her designee, and the administrator or his/her designee. The pharmaceutical services committee develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice.

(d) Reference material regarding the use of medication, adverse reactions, toxicology, and poison control center information shall be available to facility staff.

(e) There shall be procedures established for the reporting and recording of medication errors and adverse drug reactions.

(2) A staff pharmacist or consultant pharmacist shall be responsible for coordinating pharmaceutical services which include:

(a) Provision of pharmaceutical services evaluations and recommendations to the administrative staff.

(b) On-site reviews to ensure that drug handling and utilization procedures are carried out in conformance with recognized standards of practice.

(c) Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems and documenting recommendations.

(d) Provision of drug information to the nursing home staff and physicians as needed.

(e) Planning and participating in the nursing home staff development program.

(f) Consultation regarding resident care services with other departments.

(3) Security and storage of drugs.

(a) The nursing home shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as defined by regulation and accepted standards of practice.

(b) All drugs shall be stored in locked cabinets, rooms, or carts, and shall be accessible only to personnel licensed to administer or dispense drugs.

(c) Schedule III controlled substances shall be stored apart from other drugs on a separate shelf or in a separate compartment or cabinet, provided, however, Schedule III controlled substances may be stored with Schedule II controlled substances. Schedule III controlled substances can be stored with other drugs when distributed in a unit dose drug distribution system.

(d) Drugs for external use shall be stored apart from drugs for internal use, on a separate shelf or in a separate compartment or cabinet. Any shelf, compartment, or separate cabinet used for storage of external drugs shall be clearly labeled to indicate it is to be used for external drugs only.

(e) At all times, all keys to drug boxes, cabinets, and rooms shall be carried by persons legally authorized to administer drugs and on duty on the premises.

(f) If a supplemental dose kit within a unit dose drug distribution system is provided it must comply with WAC 246-865-040.

(g) If an emergency kit is provided, it shall comply with Washington state board of pharmacy regulations WAC 246-865-020 and 246-865-030.

(4) Labeling of drugs.

(a) The label for each legend drug which is not dispensed in a unit dose shall have the name and address of the

pharmacy from which the drug was dispensed; the prescription number; the physician's name; the resident's full name; the date of issue; the initials of the dispensing pharmacist; the name and strength of the drug; a controlled substances schedule, if any; the amount (e.g., number of tablets or cc's) of the drug dispensed, and the expiration date. In the case of a compounded drug which contains Schedule II or III controlled substances, the quantity of each controlled substance per cc or teaspoonful shall be shown on the label.

(b) In a unit dose drug distribution system, a clear, legible label shall be printed or affixed securely to each unit dose package. Each unit dose drug label shall include: the name, strength and, for each unit dose package, the dosage amount of the drug; the expiration date for any time-dated drug; the lot or control number; and controlled substances schedule number, if any. Each individual drug compartment shall be labeled with the full name of the resident whose drug the compartment contains and the name of the resident's physician.

(c) Nonlegend drugs shall be clearly labeled with at least the patient's name, date of receipt by the facility, as well as display a manufacturer's original label or a pharmacy label if repackaged by the pharmacist. Nonlegend drugs supplied by the extended care facility pursuant to WAC 388-88-050 need not be labeled with the patient's name.

(d) A label on a container of drugs shall not be altered or replaced except by the pharmacist. Drug containers having soiled, damaged, incomplete, or makeshift labels shall be returned to the pharmacy for relabeling or disposal. Drugs in containers having no labels or illegible labels shall be destroyed.

(5) Control and accountability.

(a) The nursing home shall maintain and follow written procedures which provide for the accurate control and accountability of all drugs in the nursing home.

(b) No drugs may be returned from the nursing home to a pharmacy except as provided in paragraph (4)(d) or if the drug is returned in unopened unit dose packages.

(c) Drugs shall be released to a resident upon discharge only on specific written authorization of the attending physician. A receipt containing information sufficient to document the drug's destination, the person who received the drug, and the name and quantity of drugs released shall be entered in the resident's health record.

(d) All of an individual resident's drugs including Schedule III, IV and V controlled substances, that are discontinued by the physician and remain unused, shall be destroyed by a licensed nurse employee of the nursing home in the presence of a witness within 90 days after having been discontinued, and accurate records of destruction maintained except from drugs which are sealed in unit dose packages.

(e) Outdated, unapproved, contaminated, deteriorated, adulterated, or recalled drugs shall not be available for use in the nursing home.

(f) Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy.

(6) Special requirements for controlled substances.

(a) All Schedule II controlled substances shall be stored in separately keyed and locked secure storage within a drug facility.

(b) Schedule III controlled substances shall be stored apart from other drugs and may be stored on a separate shelf, drawer, or compartment with Schedule II controlled substances.

(c) There shall be a record book for Schedule II and Schedule III controlled substances which shall be a bound book with consecutively numbered pages in which complete records of receipt and withdrawal of Schedule II and III controlled substances are maintained.

(d) At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s).

(e) When a resident is discharged, a record of release for any Schedule II or III controlled substances released shall be entered on the appropriate page for the given drug in the controlled substances record book.

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(f) Any discrepancy in actual count of Schedule II or III controlled substances and the record shall be documented in the Schedule II or III controlled substances books and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven calendar days shall be reported to the consultant pharmacist and the Washington state board of pharmacy.

(g) Discontinued Schedule II controlled substances and all Schedule II controlled substances which remain after the discharge or death of residents shall:

(i) Be destroyed at the nursing home within 30 days by two of the following individuals: A licensed pharmacist, the director of nursing or a registered nurse designee, and a registered nurse employee of the nursing home with appropriate documentation maintained, or

(ii) Be destroyed at the nursing home by a representative of the Washington state board of pharmacy if so requested by the board or the nursing home.

(h) A nursing home may establish procedures which vary from those paragraphs (6)(a)(g) if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances.

(7) Drug administration.

(a) Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents.

(i) Drugs shall be administered only by persons licensed to administer drugs.

(ii) The resident shall be identified prior to administration.

(b) All drugs shall be identified up to the point of administration.

(c) Drugs shall be prepared immediately prior to administration and administered by the same person who prepares them except under a unit dose system.

(d) Drug administration shall be documented as soon as possible after the act of administration, and shall include:

(i) Verification of administration

(ii) Reasons for ordered doses not taken

(iii) Reasons for administration of, and response to drugs given on and as needed basis (PRN).

(e) Drug orders shall be received only by a licensed nurse and administered only on the written or verbal order of a practitioner. Verbal orders shall be signed by the prescribing practitioner in a timely manner.

(f) The self-administration of medication program shall provide evidence of:

(i) Assessment of the resident's capabilities

(ii) Instructions for administration

(iii) Monitoring of progress and compliance with orders

(iv) Safe storage of drugs.

[Statutory Authority: RCW 18.64.005. 94-02-077, § 246-865-060, filed 1/5/94, effective 2/5/94; 92-12-035 (Order 277B), § 246-865-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 88-11-007 (Order 214), § 360-13-066, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). 81-14-055 (Order 161), § 360-13-066, filed 6/30/81.]

246-865-070

Provision for continuity of drug therapy for residents.

When a resident of a long term care facility has the opportunity for an unscheduled therapeutic leave that would be precluded by the lack of an available pharmacist to dispense drugs prescribed by an authorized practitioner, a registered nurse designated by the facility and its consultant or staff pharmacist and who agrees to such designation, may provide the resident or a responsible person with up to a 72-hour supply of a prescribed drug or drugs for use during that leave from the resident's previously dispensed package of such drugs. The drugs shall only be provided in accordance with protocols developed by the pharmaceutical services committee and the protocols shall be available for inspection. These protocols shall include the following:

(1) Criteria as to what constitutes an unscheduled therapeutic leave requiring the provision of drugs by the registered nurse;

(2) Procedures for repackaging and labeling the limited supply of previously dispensed drugs by the designated registered nurse that comply with all state and federal laws concerning the packaging and labeling of drugs;

(3) Provision to assure that none of the medication provided to the resident or responsible person may be returned to the resident's previously dispensed package of such drug or to the facility's stock.

(4) A record-keeping mechanism that will provide for the maintenance of a permanent log that includes the following information:

(a) The name of the person to whom the drug was provided;

(b) The drug and quantity provided;

(c) The date and time that the request for the drug was made;

(d) The date and time that the drug was provided;

(e) The name of the registered nurse that provided the drug;

(f) The conditions or circumstances that precluded a pharmacist from providing the drug.

Refer to WAC 246-839-810 for related regulations on this practice.

[Statutory Authority: RCW 18.64.005. 92-12-035 (Order 277B), § 246-865-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-865-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. 83-10-013 (Order 174), § 360-13-100, filed 4/26/83.]

Highlights of State of Washington Boarding Home Licensing Rules Especially Relevant to Pharmacy Practice, Chapter 388-78A WAC

(update 7-30-04—all parts effective 9-01-05)

1. A "Boarding Home" is any home or other institution that is advertised, announced or maintained with the purpose of providing for seven or more residents:

housing
basic services (housekeeping, meals, nutritious snacks, laundry and activities)
general responsibility for the safety and well-being or residents (special diets, resident monitoring, coordination of care, medication assistance as permitted)

It may also provide "**domiciliary care**" as defined as:
assistance with ADLs
health support services (diets, dementia care, mental health, blood glucose testing)
intermittent nursing services

2. **Assisted living facilities** in Washington are licensed as boarding homes. "Assisted living services" is a package of services provided by a boarding home that has a contract with DSHS under RCW 74.39A.010 to provide personal care services, intermittent nursing services, and medication administration services in accordance with regulations. Assisted living services include housing for the resident in a private apartment-like unit.

3. "Boarding Home" does not include any independent senior housing, independent living units in a CCRC, facilities certified as group teaching homes.

4. By definition, residents of boarding homes do not require the frequent presence and frequent evaluation of a registered nurse, excluding individuals who are receiving hospice care or individuals who have a short term illness (expected to resolve within 14 days, as long as the boarding home has the capacity to meet the individual's identified needs).

5. Assessment and monitoring of boarding home residents includes:

Preadmission assessment (WAC defines topics of assessment and "qualified assessor", medication management abilities, many other evaluations.

On-going assessments: full assessment at least annually, assessment focuses on a resident's identified problems

Monitoring residents' well-being

6. **Medications**:

Four pages of the regulation describe medication services, authorization prescribing) of medications, medication refusal and follow-up, non-availability of medications, alteration of medications, storing medications (by the facility or the resident), use of medication "organizers", family assistance

with medications.

The boarding home must ensure that no staff person other than a nurse or pharmacist fills medication organizers for residents. A nurse may fill the medication organizer only when the resident understands the use of the medications **and** is totally independent with self-administration except for physical assistance required or the resident can safely direct others to administer his or her medications.

The boarding home must ensure that a licensed pharmacy has filled the medication organizer any time the boarding home is involved in storing the resident's medications, or providing medication assistance or administration services to the resident.

Highlights of State of Washington Minimum Licensing Requirements For Adult Family Homes (Chapt WAC 388-76) Especially Related to Pharmacy Practice (last update 8-22-05)

1. Adult Family Homes (AFHs) are residences which provide care for 2 to 6 people 18 or older and provide services including room, board, assistance with ADL, personal care, and social services. They may also provide nursing services and if the residents are not capable of safely managing their own medications, the AFH must provide medication services. AFHs are licensed, regulated and inspected by WA State DSHS. There is a resident manager of the AFH or the AFH contracts with a qualified resident manager.

   (3) A comprehensive assessment of a prospective resident must be conducted before
   the resident is admitted to a ADF, using a form provided by DSHS. This assessment is more complete than that required for admission to a boarding home. The required functional assessments include the candidate's ability to manage his/her own medications. The regulation defines in detail "independent with self-administration", "self-administration with assistance", and "medication administration"; the latter must be performed by a "practitioner" or by nurse delegation unless performed by a family member.

   (4) An RN, LPN or a family member of the resident may fill medication organizers from prescriptions that have been filled by a pharmacy. The medication organizer must allow prescribed and OTC medications to be readily identifiable by residents, caregivers, and the RN and LPN.

   (5) A daily medication log (MAR) is required for Rx and OTC medication administration to residents classified in their care plans as not independent for self-administration.

source: http://www.aphanet.org/medicare/mtms.pdf

Medication Therapy Management Services Definition and Program Criteria

Original: 4-May-04 (APhA MTM Services Working Group)
Last Revised: 7-Jul-04 (Pharmacy Profession Stakeholders)
Approved: 27-Jul-04 (by 11 Supporting Organizations)

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

a. Performing or obtaining necessary assessments of the patient's health status;
b. Formulating a medication treatment plan;
c. Selecting, initiating, modifying, or administering medication therapy;
d. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
f. Documenting the care delivered and communicating essential information to the patient's other primary care providers;
g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
h. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
i. Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

A program that provides coverage for Medication Therapy Management services shall include:

a. Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient*. These services are distinct from formulary development and use, generalized patient education and information activities, and other population-focused quality assurance measures for medication use.
b. Face-to-face interaction between the patient* and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods. Medication Therapy Management programs shall include structures supporting the establishment and maintenance of the patient*-pharmacist relationship.
c. Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services.
d. Payment for Medication Therapy Management Services consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for CPT & RBRVS).
e. Processes to improve continuity of care, outcomes, and outcome measures.

* In some situations, Medication Therapy Management Services may be provided to the caregiver or other persons involved in the care of the patient.

The following table and figure are from Meyer BM, Cantwell M. The Medicare prescription drug, improvement, and modernization act of 2003: implications for health-system pharmacy. Am J Health-Syst Pharm. 2004; 61:1042-1051. The Medication Therapy Management component is a very important opportunity for pharmacists.

Table 1.
Components of Medicare

Component	Eligibility for Enrollment	Benefits	Funding Source
Part A	Entitlement for most people who are over 65 years of age or have end-stage renal disease	Inpatient hospital services, skilled-nursing facilities, home health visits after a hospital or skilled-nursing facility stay	Payroll taxes held in the Hospital Insurance Trust Fund
Part B	Voluntary	Physician and other outpatient hospital services	Beneficiary premiums and general revenues
Part C (renamed Medicare Advantage)	Voluntary	Integrated Part A and Part B coverage through a managed care plan	Combined funding
Part D	Voluntary	Any prescription drug, biological product, or insulin product covered by Medicaid and used for a medically accepted indication	Beneficiary premiums and general revenues

Figure 1. Out-of-pocket drug spending in 2006 for Medicare beneficiaries under the new Medicare legislation. Benefit levels are indexed to growth in per capita expenditures for covered Part D drugs. As a result, the Part D deductible is projected to increase from $250 in 2006 to $445 in 2013; the catastrophic threshold is projected to increase from $5100 in 2006 to $9066 in 2013. Reprinted, with permission, from "The Medicare Prescription Drug Law," the Henry J. Kaiser Family Foundation, March 2004. (The Kaiser Family Foundation is a nonprofit, independent, national health care philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.) (www.kff.org/medicare/medicarebenefitataglance.cfm).