

ADMINISTRATIVE AGENCY RULE REPORT
75 O.S. Supp. 2000, § 303.1
SUBMITTED TO THE GOVERNOR AND TO THE LEGISLATURE

- 1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:**
October 1, 2013, Vol. 31, No. 2 Ok Reg 12, Docket No. 13-1194

- 2. Name and address of the Agency:**
Oklahoma State Department of Health
1000 N.E. Tenth Street
Oklahoma City, Oklahoma 73117-1299

- 3. Title and Number of the Rule:**
Title 310. Oklahoma State Department of Health
Chapter 675. Nursing and Specialized Facilities

- 4. Citation to the Statutory Authority for the Rule:**
Title 63 O.S. Section 1-104; and Title 63 O.S. § 1-1950(C)(1).

- 5. Brief Summary of the Content of the Adopted Rule:**
This proposal amends rules promulgated in accordance with 63 O.S. Section 1-1950(C)(1) which authorized the State Board of Health to promulgate rules necessary for proper control and dispensing of nonprescription drugs in nursing facilities. This proposed rule amendment deletes the requirement in OAC 310:675-9-9.1(i)(8) which limits the bulk nonprescription drugs that nursing facilities may maintain for residents. The current requirement provides that only oral analgesics, antacids, and laxatives may be dispensed from bulk supplies. This change will allow nursing facilities to maintain bulk supplies of other nonprescription drugs, such as cough medicines.

- 6. Statement explaining the Need for the Adopted Rule:**
Affected persons included residents and their families as well as owners, operators, and staff of Nursing and Specialized Facilities. These parties will benefit from greater access to bulk nonprescription drugs that nursing facilities may maintain for residents and the attendant reduction in expenses available through bulk purchasing.

- 7. Date and Location of the Meeting at which such Rules Were Adopted:**
Adopted January 14, 2014, in the offices of the Oklahoma State Department of Health.

- 8. Summary of the Comments and Explanation of Changes or Lack of any Change Made in the Adopted Rules as a Result of Testimony Received at Public Hearings:**
Comments were received indicating the original limitations addressing oral analgesics, antacids, and laxatives for bulk dispensing be retained while adding permissions for drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. The Department concurred and incorporated these recommendations. A more comprehensive summary is addressed in Exhibit A.

9. List of Persons or Organizations Who Appeared or Registered For or Against the Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have Commented in Writing Before or After the Hearing:

Rebecca Moore, Executive Director; Oklahoma Assoc. of Health Care Providers, appeared at the Public Comment Hearing held November 1, 2013, and voiced support for the rule amendment.

A regular meeting of the Long-Term Care Facility Advisory Board was held on October 9, 2013. The Department provided the Advisory Board the proposed rule. Comments received are addressed in Exhibit A. A quorum of the Board was not present to allow a formal vote in support of the proposed rule changes. The members present expressed a consensus opinion in support of changes to the rule language. Board members present: Kay Parsons, Chair; Dewey Sherbon, Vice Chair; Theo Crawley; Luke Tallant; Alan Mason; Wendell Short; Dustin Cox; Ivoria Holt; Linda Brannon; Donna Bowers; Diana Sturdevant; and Willie Burkhart.

Marietta Lynch, provider, Gara Wilsie, Sequoia Health Services, Rebecca Moore, Oklahoma Association of Health Care Providers, provided written comment in support of the rule.

10. Rule Impact Statement: Hereto annexed as Exhibit B.

11. Incorporation by Reference Statement: "n/a"

12. Members of the Governing Board of the Agency Adopting the Rules and the Recorded Vote of Each Member:

Murali Krishna, President, M.D. – aye
Ronald Woodson, Vice-President, M.D. – aye
Martha Burger, M.B.A, Secretary-Treasurer – absent
Jenny Alexopoulos, D.O. – aye
Charles W. Grim, D.D.S., M.H.S.A. – aye
Terry Gerard, D.O. – aye
Robert S. Stewart, M.D. – aye
Tim Starkey, M.B.A. – aye
Cris Hart-Wolfe – aye

13. Additional information: Information regarding this rule may be obtained by contacting Mike Cook, Assistant Chief, Long Term Care Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to mikec@health.ok.gov.

RULE COMMENT SUMMARY AND RESPONSE

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 675. NURSING AND SPECIALIZED FACILITIES

The rule report submitted to the Governor, the Speaker of the House of Representatives and the President Pro Tempore of the Senate, pursuant 75:303.1(A) of the Administrative Procedures Act, shall include: (9) *A summary of the comments and explanation of changes or lack of any change made in the adopted rules as a result of testimony received at all hearings or meetings held or sponsored by an agency for the purpose of providing the public an opportunity to comment on the rules or of any written comments received prior to the adoption of the rule. The summary shall include all comments received about the cost impact of the proposed rules;* (10) *A list of persons or organizations who appeared or registered for or against the adopted rule at any public hearing held by the agency or those who have commented in writing before or after the hearing.*[75:303.1(E)(9)&(10)]

Rule Subchapter and Section: Subchapter 9. Resident Care Services; Section 310:675-9-9.1, Medication services

The comments below concern the sole section for amendment described above.

Name & Organization: Rebecca Moore, Executive Director; Oklahoma Assoc. of Health Care Providers.

Comment: Ms. Moore appeared at the Public Comment Hearing held November 1, 2013, and voiced support for the rule amendment and the Department's inclusive rulemaking process.

Response: The Department appreciates the favorable review of the proposed rules. No changes to the proposed rules are necessary based on the comments received.

Name & Organization: Regular Meeting of the Long-Term Care Facility Advisory Board; October 9, 2013.

LTCFAB members present: Kay Parsons, Chair; Dewey Sherbon, Vice Chair; Theo Crawley; Luke Tallant; Alan Mason; Wendell Short; Dustin Cox; Ivoria Holt; Linda Brannon; Donna Bowers; Diana Sturdevant; and Willie Burkhart.

Guests present: Mary Brinkley, Leading Age OK; Marilyn Kipps, guest; Jim Kipps; Gina Stafford, OK Board of Nursing; Oralene Sherbon, general public; Joyce Clark, Achievis; Marietta Lynch, Oklahoma Association of Health Care Providers; Wes Bledsoe, A Perfect Cause; Bill Whited, State Long Term Care Ombudsman's Office; Greg Frogge, McAfee Taft; Trish Ewing, State Council on Aging; Mark Stratton, University of Oklahoma Department of Pharmacy; Keith Swanson, OU School of Pharmacy; Gara Wilsie, Sequoia Health Services.

Comment: The Department provided the Advisory Board the Notice of Rulemaking Intent, Draft Rule Impact Statement and Proposed Rule. At this meeting, the attendees named above provided additional input to the proposed rule language. Comments received were expressing concern that the proposed language was not broad enough as far as medications that would be eligible for bulk purchase and would not serve both residents and facilities as hoped. Participants and experts present provided important information about maintaining the safety to residents and the complex process and medication protocols involved in ordering and administering the medications to reassure those with safety and quality control concerns. New language proposed at this meeting was crafted as a result of this feedback. A quorum of the Board was not present to allow a formal vote in support of the proposed rule changes. The members present expressed a consensus opinion in support of changes to the rule language.

Members were advised of the Public Comment Hearing to be held November 1, 2013 at which time they could provide individual written or oral comments.

Response: The Department appreciates the constructive feedback of the proposed rule language. See the proposed response below to address these and other comments.

Name & Organization: Marietta Lynch, provider, Gara Wilsie, Sequoia Health Services, Rebecca Moore, Oklahoma Association of Health Care Providers, email, October 30, 2013

Comments: The Department distributed revised language and received feedback from the persons listed above. Concern was expressed that the draft needed some tweaking. The draft language distributed was a little different from what was proposed at the LTCFAB meeting. The feedback indicated that the original limitations addressing oral analgesics, antacids, and laxatives for bulk dispensing be retained while adding permissions for drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses.

Response: The Department appreciates the constructive feedback of the proposed rule language. After review, the Department concurs with the proposed recommendations. Long Term Care is moving forward with the agreed proposed changes to the language for the rule. The Department proposes the revision as shown below.

310:675-9-9.1. Medication services

(8) **Allowed nonprescription drugs.** Facilities may have only oral analgesics, antacids, and laxatives for bulk dispensing and/or drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. Non formulary over the counter medications may be prescribed if the resident has therapeutic failure, drug allergy, drug interaction or contraindications to the formulary over the counter medication. ~~No other categories of medication may be maintained as bulk medications.~~

Agency Rule Contact:

Mike Cook, Assistant Chief, Long Term Care Service, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207, phone 405-271-6868, or by e-mail to mikec@health.ok.gov

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 675. NURSING AND SPECIALIZED FACILITIES

Before the Oklahoma State Board of Health December 10, 2013

1. DESCRIPTION:

This proposal amends rules promulgated in accordance with 63 O.S. Section 1-1950(C)(1) which authorized the State Board of Health to promulgate rules necessary for proper control and dispensing of nonprescription drugs in nursing facilities.

Section 310:675-9-9.1(i) addresses those procedures for maintaining nonprescription drugs for dispensing from a common or bulk supply. This proposed rule amendment deletes the requirement in OAC 310:675-9-9.1(i)(8) which limits the bulk nonprescription drugs that nursing facilities may maintain for residents. The current requirement provides that only oral analgesics, antacids, and laxatives may be dispensed from bulk supplies. This change will allow nursing facilities to maintain bulk supplies of other nonprescription drugs, such as cough medicines.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Affected persons will be residents and their families as well as owners, operators, and staff of Nursing and Specialized Facilities. These parties will benefit from greater access to bulk nonprescription drugs that nursing facilities may maintain for residents and the attendant reduction in expenses availability through bulk purchasing.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

Affected persons will be residents and their families as well as owners, operators, and staff of Nursing and Specialized Facilities. These parties will benefit from greater access to bulk nonprescription drugs that nursing facilities may maintain for residents and the attendant reduction in expenses availability through bulk purchasing. The Department sought comment the public and providers on the value of the benefit and expected health outcomes during the comment period. Comments received were expressing concern that the proposed language was not broad enough as far as medications that would be eligible for bulk purchase and would not serve both residents and facilities as hoped. Participants and experts present provided important information about maintaining the safety to residents and the complex process and medication protocols involved in ordering and administering the medications to reassure those with safety and quality control concerns. . The feedback indicated that the original limitations addressing oral analgesics, antacids, and laxatives for bulk dispensing be retained while adding permissions for drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. The number of residents that might benefit is estimated at approximately nineteen thousand (19,000), the approximate statewide nursing facility census at the time of this report.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

These Rules involve no additional fees. Elimination of the restrictions on bulk medications has the potential to reduce medication costs for residents and facilities.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The cost to the Department to implement the amendments will be approximately \$4,000 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Public comment will be sought on the effects on public health and safety.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Public comment will be sought on any detrimental effects on public health and safety.

11. This rule impact statement was prepared on August 16, 2013 and revised November 14, 2013.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 675. NURSING AND SPECIALIZED FACILITIES**

SUBCHAPTER 9. RESIDENT CARE SERVICES

310:675-9-9.1. Medication services

(a) Storage.

(1) Medications shall be stored in a medication room, a locked cabinet, or a locked medication cart, used exclusively for medication storage.

(2) The medication storage area temperature shall be maintained between 60° F. (15.5° C.) to 80° F.(26.6° C.)

(3) The medication room, the medication storage cabinet, and medication cart shall be locked when not in use.

(4) The key to the medication storage areas shall be in the possession of the person responsible for administering medications.

(5) Scheduled medications shall be in a locked box within the locked medication area or cart.

(6) Medications for external use shall be stored separately from medications for internal use.

(7) Medications requiring refrigeration shall be kept within a temperature range of 36° F. (2.2° C.) to 48° F. (8.8° C.) and separated from food and other items. There shall be a method for locking these medications.

(8) The medication areas shall be well lighted, clean and organized.

(9) Running water shall be in close proximity to the medication area.

(10) Powdered over-the-counter medication for topical use may be kept in the resident's room for administration by a nurse aide if:

(A) The facility develops and implements policies and procedures for safe storage and application of the powder; and

(B) Each aide who applies the over-the-counter topical medication is trained in accordance with the established policies and procedures of the facility.

(b) Emergency medications. Emergency medication, policies and equipment shall include but not be limited to:

(1) An electric suction machine with necessary aseptic aspirator tips.

(2) An emergency tray or cart with the following items labeled and accessible to licensed personnel only: resuscitation bag; tongue depressors; and assorted airways; sterile hypodermic syringes in 2 cc, 5 cc, and 20 cc or larger sizes and

appropriate needles. The content shall be limited to emergency medications and contain no scheduled medications. Only two single dose vials of the following medications may be on the tray or cart: 50% Dextrose, respiratory stimulant, a cardiac stimulant, injectable lasix, injectable dilantin and injectable benadryl.

(3) A certified medication aide shall not administer injectable medications from any emergency tray or cart, but shall have access to resuscitation bags, tongue depressors, and assorted sizes of airways.

(c) **Medication accountability.**

(1) Medications shall be administered only on a physician's order.

(2) The person responsible for administering medications shall personally prepare the dose, observe the swallowing of oral medication, and record the medication. Medications shall be prepared within one hour of administration.

(3) An accurate written record of medications administered shall be maintained. The medication record shall include:

(A) The identity and signature of the person administering the medication.

(B) The medication administered within one hour of the scheduled time.

(C) Medications administered as the resident's condition may require (p.r.n.) are recorded immediately, including the date, time, dose, medication, and administration method.

(D) Adverse reactions or results.

(E) Injection sites.

(F) An individual inventory record shall be maintained for each Schedule II medication prescribed for a resident.

(G) Medication error incident reports.

(4) A resident's adverse reactions shall be reported at once to the attending physician.

(d) **Medication labels and handling.**

(1) All prescribed medications shall be clearly labeled indicating the resident's full name, physician's name, prescription number, name and strength of medication, dosage, directions for use, date of issue and expiration, and name, address and telephone number of pharmacy or physician issuing the medication, and the quantity. If a unit dose system is used, medications shall indicate, at least, the resident's full name, physician's name and strength of medication, and directions for use.

(2) When over-the-counter medications are prescribed and obtained in the original manufacturers container, the package directions shall be considered part of the label. The resident's name shall be on the package.

(3) Each resident's medications shall be kept or stored in the originally received containers. Paper envelopes shall not be considered containers.

(4) Medication containers having soiled, damaged, illegible or makeshift labels shall be relabeled by the issuing pharmacy or physician. Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label on a medication container except for over-the-counter medication containers.

(5) No person shall change labels on medication containers. If the attending physician orders a change of directions, there shall be a procedure to mark the container indicating a label change is needed at the next prescription refill.

(6) A pharmacist shall dilute, reconstitute and label medications, whenever possible. If not possible, a registered nurse may reconstitute, dilute and label medications. A distinctive, indelible, supplementary label shall be affixed to the medication container when diluted or reconstituted for other than immediate use. A licensed practical nurse may reconstitute oral medications only. The label shall include the following: resident's name, dosage and strength per unit/volume, nurse's initials, expiration date, and date and time of dilution or reconstitution.

(7) When a resident is discharged, or is on therapeutic leave, the unused medication shall be sent with the resident, or with the resident's representative, unless there is a written physician's order to the contrary, or the medication has been discontinued, or unless the resident or the resident's representative donates unused prescription medications for dispensation to medically indigent persons in accordance with the Utilization of Unused Prescription Medications Act. The clinical record shall document the quantity of medication sent, and returned or donated, and the signature of the person receiving or transferring the medications.

(8) All medication orders shall be automatically stopped after a given time period, unless the order indicates the number of doses to be administered, or the length of time the medication is to be administered. The automatic stop order may vary for different types of medications. The facility shall develop policies and procedures, in consultation with the medical director and pharmacist, to review automatic stop orders on medications. The policy shall be available to personnel administering medications.

(9) No resident shall be allowed to keep any medications unless the attending physician or interdisciplinary team has indicated on the resident's clinical record that the resident is mentally and physically capable of self-administering

medications.

(10) A resident who has been determined by the physician or interdisciplinary team as capable of self-administering medication may retain the medications in a safe location in the resident's room. The facility shall develop policies for accountability. Scheduled medications shall not be authorized for self-administration, except when delivered by a patient controlled analgesia pump.

(11) A physician's telephone orders shall be conveyed to, recorded in the clinical record, and initialed by the licensed nurse receiving the orders.

(12) Medications shall be administered only by a physician, registered nurse, a licensed practical nurse, or a certified medication aide. The only injectables which a certified medication aide may administer are insulin and vitamin B-12 and then only when specifically trained to do so.

(13) A pharmacy, operating in connection with a facility, shall comply with the State pharmacy law and the rules of the Oklahoma State Board of Pharmacy.

(14) Powdered over-the-counter medication for topical use may be administered by a trained nurse aide when designated in writing by the attending physician and delegated by a licensed nurse. The licensed nurse shall ensure that the aide demonstrates competency in reporting skin changes, storage, application and documentation policies and procedures. The licensed nurse or the attending physician shall document in the resident's record a skin assessment at least twice each week and more often if required by the facility's approved policy.

(e) **Medication destruction.**

(1) Non-controlled medications prescribed for residents who have died and non-controlled medications which have been discontinued shall be destroyed by both the director of nursing and a licensed pharmacist or another licensed nurse. Controlled medication shall be destroyed by a licensed pharmacist and the Director of Nursing. The facility may transfer unused prescription drugs to city-county health department pharmacies or county pharmacies in compliance with the Utilization of Unused Prescription Medications Act and all rules promulgated thereunder. Prescription only medications including controlled medications shall not be returned to the family or resident representatives. The destruction and the method used shall be noted on the clinical record.

(2) Medications prescribed for one resident may not be administered to, or allowed in the possession of, another resident.

(3) There shall be policies and procedures for the destruction of discontinued or other unused medications within a reasonable

time. The policy shall provide that medications pending destruction shall not be retained with the resident's current medications. The destruction of medication shall be carried out in the facility and a signed record of destruction shall be retained in the facility.

(f) **Medication regimen review.** The facility shall ensure that each resident's medications are reviewed monthly, by a registered nurse or a licensed pharmacist. The reviewer shall notify the physician and director of nursing, in writing, when irregularities are evident.

(g) **Consultant pharmacist.** The facility shall have a consultant licensed pharmacist to assist with the medication regimen review and medication destruction. The consultant pharmacist shall discuss policies and procedures for the administration, storage, and destruction of medications with the administrator, director of nursing and other appropriate staff.

(h) **Emergency pharmacy.** The facility shall have a contract, or letter of agreement, with a licensed pharmacy that agrees to serve as the emergency pharmacy. The emergency pharmacy shall be available twenty-four hours a day.

(i) **Bulk nonprescription drugs.** A facility may maintain nonprescription drugs for dispensing from a common or bulk supply if all of the following are accomplished.

(1) **Policy of facility.** The facility must have and follow a written policy and procedure to assure safety in dispensing and documentation of medications given to each resident.

(2) **Acquisition.** The facility shall maintain records which document the name of the medication acquired, the acquisition date, the amount and the strength received for all medications maintained in bulk.

(3) **Dispensing.** Only licensed nurses, physicians, pharmacists or certified medication aides (CMA) may dispense for administration these medications and only upon the written order for as needed (p.r.n.) or nonscheduled dosage regimens dosing from a physician as documented in the clinical record of the resident.

(4) **Storage.** Bulk medications shall be stored in the medication area and not in resident rooms.

(5) **Records.** The facility shall maintain records of all bulk medications which are dispensed on an individual signed medication administration record (MAR).

(6) **Labeling.** The original labels shall be maintained on the container as it comes from the manufacturer or on the unit-of-use (blister packs) package.

(7) **Package size.** The maximum size of packaging shall be established by the facility in its policy and procedures and shall insure that each resident receives the correct dosage;

provided however, that no liquid medications shall be acquired nor maintained in a package size which exceeds 16 fluid ounces.

(8) **Allowed nonprescription drugs.** Facilities may have only oral analgesics, antacids, and laxatives for bulk dispensing and/or drugs listed in a facility formulary developed or approved by the consultant pharmacist, medical director and director of nurses. Non formulary over the counter medications may be prescribed if the resident has therapeutic failure, drug allergy, drug interaction or contraindications to the formulary over the counter medication. ~~No other categories of medication may be maintained as bulk medications.~~