Dear Senators LODGE, Broadsword & Werk, and
Representatives BLOCK, Nielsen & Henbest:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Idaho Board of Pharmacy:

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0808).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 10-27-08. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 11-24-08.

_____The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-2475, or send a written request to the address or FAX number indicated on the memorandum enclosed.

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Research & Legislation Staff - Paige Alan Parker

DATE: October 8, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0808 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0808 (hereinafter "proposed rule"), amending the Board's rules found at IDAPA 27.01.01. According to the Board, the proposed rule is authorized pursuant to sections 37-2715 and 54-1717, Idaho Code.

Chapter 27, title 37, Idaho Code is the Uniform Controlled Substances Act. Section 37-2715, Idaho Code, permits the Board to promulgate rules relating to the dispensing of controlled substances within Idaho. Chapter 17, title 54, Idaho Code, is the Idaho Pharmacy Act. Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy.

According to the Board, the proposed rule is in response to a joint report issued by the National Association of Boards of Pharmacy and the American Society of Consultant Pharmacists which recommended that states update their pharmacy practice rules to keep pace with the evolution of the practice of long-term care pharmacy in order to better serve the residents of long-term care facilities. Accordingly, the proposed rule deals with the practice of pharmacy in institutional facilities by defining terms, by permitting chart orders to serve as prescription drug orders, by specifying the use of chart and drug orders, by clarifying the use of prepackaging and by permitting a pharmacy under contract with an institutional facility to contract with another pharmacy for the limited purpose of assuring that drugs or devises are attainable to meet the immediate needs of patients and residents.

According to the Board, no fee or charge is imposed by the temporary and proposed rule. The Board states that there is no anticipated impact to the general fund greater than $10,000 during the fiscal year as a result of the temporary and proposed rule. According to the Board, negotiated rulemaking was not conducted because of the simple nature of the rulemaking. The Board states that public hearing(s) will be scheduled if requested in writing by 25 persons, a political subdivision, or an agency, not later than October 15, 2008. All written comments must

be delivered to the Board on or before October 22, 2008.

ANALYSIS

At section 252, dealing with pharmacy practice in institutions, the proposed rule defines five new terms, "long-term care facility," "centralized prescription filling," "centralized prescription processing," "chart order," and "prepackaging," and modifies two definitions, "institutional facility" and "institutional pharmacy." None of these terms have statutory equivalents.

Under the proposed rule, "long-term care facility" means "a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients." Section 252.01.b. "Centralized prescription filling" and "centralized prescription processing" are the filling or processing "by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order." Sections 252.01.d and e.

"Chart order" is a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a practitioner or his designated agent for a drug or device and shall be considered a prescription drug order provided that it contains specified information. Section 252.01.f. This definition contains elements of "drug order" as defined at section 54-1705(8), Idaho Code, and "prescription drug order" defined at section 54-1705(29), Idaho Code. The major differences in these definitions is that "chart order" is entered on the chart or medical record of an inpatient or resident of an institutional facility, whereas a "drug order" and a "prescription drug order" may be verbal if they meet certain transmission and reduce-to-writing requirements. The specified information required for a "chart order" is similar, but not identical, to the information required for a "drug order." For example, a "chart order" requires "name, strength, and dosage form of the drug prescribed" and "directions for use," sections 252.01.f.iii and iv, while a "drug order" requires more detailed information, including "the name and strength or size of the drug or device, unless specified by individual institution policy or guideline, the amount to be dispensed, either in quantity or days, adequate directions for the proper use of the drug or device when it is administered to the patient," section 54-1705(8), Idaho Code. This variation of specific requirements may cause confusion.

"Prepackaging" is "the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred." Section 252.01.g.

The proposed rule modifies the definition of "institutional facility" by adding the newly defined term "long-term care facility" to the list of facilities or institutions falling within the definition. Section 252.01.a. "Institutional pharmacy" is modified by adding the newly defined term "prepackaging" to the list of activities in which the institutional pharmacy may engage. Section 252.01.c.

The proposed rule modifies the procedure to be followed when drugs are to be removed from an emergency kit (i.e., drugs which may be required to meet the immediate therapeutic needs of patients and which are not timely available from any other authorized source). Under the proposed rule, drugs may be removed from an emergency kit pursuant to a chart order. However such an order is not required for the supplying pharmacist to replace expired drugs with current dated drugs. Section 253.08.

The proposed rule adds "chart order" to the orders that authorize an institutional pharmacy director to dispense drugs within the facility, section 255.03.f, that are required from an authorized physician before an institutional facility may disperse drugs, section 255.06, that authorize the administration of drugs at an institutional facility, section 256.01, and that authorize the administration of drugs that a patient may bring into an institutional facility, section 257.03.a. The minimum requirements for drug orders have been modified by the proposed rule to cross reference the requirements contained in the newly defined term "chart order." Section 255.09.

The proposed rule adds a new subsection 02 on "Centralized Prescription Processing or Filling for Immediate Need" to section 257 on "Drugs from Outside Sources." This new subsection: (1) permits an outside pharmacy that does not have an institutional pharmacy at an institutional facility to outsource prescription processing or filling services to another pharmacy; and (2) prescribes the conditions to be met for such outsourcing (i.e., to assure that the drugs or devices are attainable to meet immediate needs or where the outsourcing pharmacy cannot provide its services on an ongoing basis; approval has been obtained from the institutional facility; a valid chart order has been provided to the outsource pharmacy; and there is a written contract between the pharmacies).

SUMMARY

The Department's proposed rule change appears to be authorized under sections 37-2715, and 54-1717, Idaho Code.

cc: Idaho State Board of Pharmacy
Mark D. Johnston

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0808

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Sections 37-2715 and 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 15, 2008.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The National Association of Boards of Pharmacy (NABP) partnered with the American Society of Consultant Pharmacists (ASCP) to address areas of pharmaceutical care in the context of long-term care facilities, which are largely populated by the nation's growing number of seniors. In March 2007, the NABP and ASCP issued the "NABP/ASCP Joint Report: Model Rules for Long-Term Care Pharmacy Practice." The Joint Report recommends that states update their pharmacy practice rules to keep pace with the evolution of the practice of long-term care pharmacy in order to better serve the interests of and protect the health, safety, and welfare of the residents of long-term care facilities; and it has proposed various changes to the NABP Model Rules. The Board believes that the conclusions and recommendations of the Joint Report are well-taken and that it is in the interests of the public in Idaho for the Board to amend its rules regarding the practice of pharmacy in institutions in order to adopt recommendations of the Joint Report where appropriate. The proposed rulemaking amends rules which are related to the practice of pharmacy in institutional facilities; amends the rules to include "Long-Term Care Facility" within the definition of "Institutional Facility;" to define "Long-Term Care Facility;" to define "Chart Order;" and to define "Prepackaging;" amends the rules to permit chart orders to serve as a prescription drug order in institutional facilities; amends the rules to specify the use of chart orders as it relates to removal of drugs from emergency kits, to drugs orders for inpatient use, to drug order for outpatient use, to the administration of drugs in institutional facilities, and to the administration of the patient's own drugs when brought into the institutional facility; amends the rules to clarify to use of prepackaging in institutional facilities, including, but not limited to, prepackaged drugs dispensed from hospital emergency rooms by registered nurses; amends provisions dealing with the responsibility of the director of the institutional pharmacy for the dispensing of all drugs within the facility upon receipt of a physician's order to include a chart order; and amends the rule to permit, in certain circumstances, pharmacies which provide pharmaceutical care services under a contract with an institutional facility that does not have an institutional pharmacy to contract with another pharmacy for the limited purpose of assuring that drugs or devises are attainable to meet the immediate needs of patients and residents of the institutional facility when the first pharmacy cannot provide such services to meet the immediate need.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking: None.

NEGOTIATED RULEMAKING: Pursuant to 67-5220(1), Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 22, 2008.

DATED this 13th day of August, 2008.

Mark D. Johnston, R.Ph.
Executive Director
Idaho Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE TEXT OF DOCKET NO. 27-0101-0808

252. PHARMACY PRACTICE IN INSTITUTIONS.

01. Definitions. For purposes of these rules the following apply: (7-1-93)

a. Institutional Facility is defined as: Hospital, Skilled Nursing Care Facility, Intermediate Care Facility, Extended Care Facility, Long-Term Care Facility, and any other such ~~*organization*~~ facility or institution, including those operated by the state of Idaho, whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where physicians, dentists, veterinarians, osteopaths, or other practitioners of the healing arts who are duly licensed, engage in private practice. ~~*(7-1-93)*~~( )

b. Long-Term Care Facility is defined as a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients. ( )

~~*b*~~**c.** Institutional Pharmacy is defined as that portion of an Institutional Facility which is engaged in the distribution, prepackaging, or manufacture, production or sale of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs") and which shall be registered with the Board pursuant Title 54, Chapter 17, Idaho Code. ~~*(7-1-93)*~~( )

d. Centralized Prescription Filling is defined as the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order. ( )

e. Centralized Prescription Processing is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order. ( )

f. Chart Order is defined as a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a practitioner or his designated agent for a drug or device and shall be considered a prescription drug order provided that it contains: ( )

i. The full name of the patient; ( )

ii. Date of issuance; ( )

iii. Name, strength, and dosage form of the drug prescribed; ( )

iv. Directions for use; and ( )

v. If written, the prescribing practitioner's signature or the signature of the practitioner's agent,

including the name of the prescribing practitioner; or, if electronically submitted, the prescribing practitioner's electronic or digital signature. ( )

g. Prepackaging is defined as the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred. ( )

02. Purpose. The purpose of the following rules is to accomplish the purposes of the Idaho Pharmacy Act as specified in Section 54-1703, Idaho Code, by implementing the provisions of that portion of the Act concerning Registration of Facilities as specified in Section 54-1729, Idaho Code. (7-1-93)

03. Applicability. The following rules are applicable to all institutions and institutional pharmacies as defined in ~~*Paragraph*~~ Section 252~~*.01.a.*~~ of ~~*these*~~ this rule~~s~~. ~~*(7-1-93)*~~( )

04. Registration of Institutional Pharmacies. All institutional pharmacies shall register annually with the Board, certificates of registration shall be issued only to those institutional pharmacies which satisfy the provisions of Section 54-1729, Idaho Code, and Paragraph 251.05 through Section 259 of these rules. (7-1-93)

05. Director of Institutional Pharmacy. Each institutional pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director, who is licensed to engage in the practice of pharmacy in this state and who is knowledgeable in, and thoroughly familiar with the specialized functions of institutional pharmacies. He shall be responsible for all activities of the institutional pharmacy, and for meeting the requirements of the Idaho Pharmacy Act and these rules. (7-1-93)

06. Supportive Personnel. The Director of an institutional pharmacy shall be assisted by a sufficient number of additional registered pharmacists and ancillary personnel as may be required to operate such pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (7-1-93)

a. Trained technical personnel may be employed. The Director shall develop and implement written policies and procedures to specify the duties to be performed by such technical personnel. (7-1-93)

b. Such policies and procedures shall, at a minimum, specify that ancillary technical personnel are personally and directly supervised by a registered pharmacist and that ancillary technical personnel are not assigned duties which may be performed only by registered pharmacists. (7-1-93)

c. Secretarial and clerical assistance and support should be provided as required to assist with record keeping, report submission and other administrative duties; provided, however, such personnel do not perform any technical duties. (7-1-93)

07. Supervision by Director. All of the activities and operations of each institutional pharmacy shall be personally and directly supervised by its Director. (7-1-93)

08. Ancillary Personnel. All functions and activities of ancillary personnel shall be personally and directly supervised by a sufficient number of registered pharmacists to insure that all such functions and activities are performed competently, safely and without risk of harm to patients. (7-1-93)

09. Pharmacist Absence. During such times as an institutional pharmacy may be unattended by a registered pharmacist, arrangements shall be made in advance by the Director for provision of drugs to the medical staff and other authorized personnel of the institutional facility. (7-1-93)

10. Access to Pharmacy. One (1) supervisory registered professional nurse and only one (1), in any given eight (8) hour shift, may have access to the pharmacy and may remove drugs there from. (7-1-93)

11. Designated Nurse. Such nurse shall be designated in writing by the Director or the appropriate committee of the institutional facility and shall prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures

required. Such education and training shall be given by the Director, who shall require, at a minimum, the following records and procedures: (7-1-93)

a. Removal of any drugs from the pharmacy by an authorized nurse must be recorded on a suitable form showing name of drug, strength, amount, date, time and signature of nurse. (7-1-93)

b. Only prepackaged drugs in amounts sufficient for the immediate therapeutic needs shall be removed from the pharmacy when a pharmacist is not available. (7-1-93)

253. EMERGENCY KITS.

01. Institutional Facility. In a facility which does not have an institutional pharmacy, drugs may be provided for use by authorized personnel by emergency kits located at such facility, provided, however, such kits meet the following requirements. (7-1-93)

02. Definition -- Emergency Kit Drugs. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source. (7-1-93)

03. Supplying Pharmacy. All emergency kit drugs shall be provided by one (1) pharmacy licensed by the Board, retained for such purpose; upon retaining each such pharmacy, the institutional facility shall notify the Board in writing. Such pharmacy shall meet the requirements of Subsection 257.01 of these rules. (7-1-93)

04. Drugs Included. The supplying pharmacist and the committee responsible for pharmaceutical services of the institutional facility shall jointly determine the drugs, by identity and quantity to be included in emergency kits. (7-1-93)

05. Storage of Emergency Kits. Emergency kits shall be stored in locked areas, suitable to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them. (7-1-93)

06. Labeling, Exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and it is for use in emergencies only; and in addition, such label shall also contain a listing of the drugs contained therein, including name, strength, quantity and expiration of contents, and the name, address and telephone number of the supplying pharmacist. (7-1-93)

07. Labeling, Interior. All drugs contained in emergency kits shall be labeled in accordance with Subsection 255.04 of these rules and shall also be labeled with such other and further information as may be required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients of the facility. (7-1-93)

08. Removal of Drugs From Emergency Kit. Drugs shall be removed from emergency kits by authorized personnel only pursuant to a valid physician's order, ~~*by authorized personnel, or by*~~ including a chart order, but such an order shall not be required for the supplying pharmacist to replace expired drugs in the kit with current dated drugs. ~~*(7-1-93)*~~( )

09. Notifying Pharmacist When Kit Is Opened. Whenever an emergency kit is opened, the supplying pharmacist shall be notified within a reasonable time, and the pharmacist or pharmacist designee shall restock the kit. (7-1-97)

10. Expiration Dates. Upon the occurrence of any expiration date, the supplying pharmacist shall replace expired drugs with current dated drugs. (7-1-93)

11. Policies and Procedures. The supplying pharmacist shall, in conjunction with the committee responsible for pharmaceutical services of the institutional facility develop and implement written policies and procedures to insure compliance with the provisions of Section 253 of these rules. (7-1-93)

12. Noninstitutional Facility Home Health Nurses. An Idaho licensed pharmacy may supply certain limited emergency drug kits for state licensed or Medicare certified home health agencies. (7-1-97)

a. All Subsections of Section 253 of these rules shall apply to home health agency emergency kits except as modified in this Subsection 253.12 of these rules. (7-1-97)

b. Home health agency emergency kit drugs may only contain such drugs as specifically approved by rule of the Board. Such drugs are limited to the following: (7-1-97)

i. Epinephrine injection. (7-1-97)

ii. Diphenhydramine injection. (7-1-97)

iii. Corticosteroid injection. (7-1-97)

iv. Narcotic antagonist. (7-1-97)

v. Sterile water. (7-1-97)

vi. Sterile saline solution for injection. (7-1-97)

vii. Heparin flush. (7-1-97)

c. Storage. Home health agency emergency kits shall be stored in locked areas, suitable to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within that period. (7-1-97)

i. Provided, however, that nurses licensed by the Idaho Board of Nursing and employed by such state licensed or Medicare certified home health agencies may carry such home health agency emergency kits on their person while on duty and in the course and scope of their employment for the home health agency. When not actually on duty and within the course and scope of their employment, the nurses must return the home health agency emergency kits to the storage area identified in Paragraph 253.12.c. of these rules (7-1-97)

d. The legend drugs included in the home health agency emergency kit shall remain the property of, and under the responsibility of, the Idaho licensed supplying pharmacy. (7-1-97)

(BREAK IN CONTINUITY OF SECTIONS)

255. DRUG DISTRIBUTION AND CONTROL.

01. Purpose and Mission. The primary purpose and mission of an institutional pharmacy shall be to provide properly prepared drugs for the patients of the facility in minimum time and with maximum accuracy, safety and professionalism under written procedures established by the Director for the distribution of pharmaceutical materials so as to achieve this goal. (7-1-93)

02. Responsibility of Director. The Director shall be responsible for the safe and efficient distribution of, control of and accountability for drugs. The other professional staff of the institutional facility shall cooperate with the Director in meeting this responsibility and in ordering, administering and accounting for pharmaceutical materials so as to achieve this purpose. (7-1-93)

03. Minimum Responsibilities of Director. The Director shall be responsible for, at a minimum, the following: (7-1-93)

a. Preparation and sterilization of parenteral medications manufactured within the institutional facility. (7-1-93)

b. A mixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the institutional pharmacy. (7-1-93)

c. Manufacture of drugs, if applicable. (7-1-93)

d. Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the institutional facility. (7-1-93)

e. Participation in development of a formulary or drug list for the facility. (7-1-93)

f. Dispensing of all drugs within the facility only upon receipt of an original or a direct copy of a physician's order, including a chart order. ~~(7-1-93)~~( )

g. Filling and labeling all containers from which drugs are to be administered. (7-1-93)

h. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient-care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the institutional facility. (7-1-93)

i. Records of all transactions of the pharmacy as may be required by applicable law, rule or regulation to maintain accurate control over and accountability for all pharmaceutical materials. (7-1-93)

j. Participation in those aspects of the institutional facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness. (7-1-93)

k. Fullest cooperation with teaching and research programs in the institutional facility. (7-1-93)

l. Implementation of the policies and decisions of the appropriate committee of the institutional facility. (7-1-93)

m. Meeting all inspection and other requirements of the Idaho Pharmacy Act and these rules. (7-1-93)

04. Dispensing and Labeling of Drugs for Use Inside or Outside a Facility. (7-1-93)

a. For use inside the facility all drugs dispensed by the pharmacy intended for use within the facility shall be dispensed in appropriate containers and adequately labeled according to current acceptable professional standards. (7-1-93)

b. For use outside the facility all drugs dispensed to patients about to be discharged or to whom it is certain will carry the item dispensed outside of the facility shall be labeled with the following information: (7-1-93)

i. Name, address and telephone number of the institutional pharmacy. (7-1-93)

ii. Date and identifying serial number. (7-1-93)

iii. Full name of patient. (7-1-93)

iv. Name of drug, strength, and number of units. (7-1-93)

v. Directions for use to the patient. (7-1-93)

vi. Name of physician prescribing. (7-1-93)

vii. Initials of pharmacist dispensing. (7-1-93)

viii. Required precautionary information regarding controlled substances. (7-1-93)

ix. Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient. (7-1-93)

c. Whenever any drugs are added to parenteral admixtures, whether within or outside the direct and personal supervision of a registered pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, and name of person so adding. (7-1-93)

05. Discontinued and Outdated Drugs. The Director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition, or that the Director or his designee make proper disposition or dispose of such drugs at the storage site. (7-1-93)

06. Physician's Orders. Drugs may be dispersed from the institutional pharmacy only upon written orders or direct copies thereof from authorized physicians, including chart orders. ~~(7-1-93)~~( )

07. Authorization of Physicians. The appropriate committee of the institutional facility shall, from time to time as appropriate, designate those physicians who are authorized to issue orders to the pharmacy. (7-1-93)

08. Use of Abbreviations and Chemical Symbols. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility. (7-1-93)

09. Drug Orders for Inpatient Use. Orders for drugs for use by inpatients shall, at a minim~~al~~um contain the ~~*patient name and room number, drug name, strength, directions for use, date and physician's signature or that of his authorized representative*~~ information required of a chart order by Paragraph 252.01.f of these rules. ~~(7-1-93)~~( )

10. Drug Orders for Outpatient Uses. Orders for drugs for use by outpatients shall at a minimum, contain all of the items required by the preceding rule, and in addition, the quantity, physician's address and DEA identification number, if applicable, and patient's address, if applicable. (7-1-93)

11. Proofs of Use. Proofs of use of such controlled substances and other drugs as may be specified by the appropriate committee of the institutional facility shall be submitted to the Director, on forms provided by the Director, together with any and all unused portion of such drug. The forms shall specify, at a minimum, name of drug, dose, name of ordering physician, name of patient, date and time of administration to patient, and name of individual administering. (7-1-93)

12. Drug Recall Procedure. The Director shall develop and implement a recall procedure that can be readily activated to assure the pharmacy staff and the Director that all drugs included on the recall are returned to the pharmacy for proper disposition. (7-1-93)

13. Reporting Suspected Adverse Drug Reactions. Any and all suspected adverse drug reactions shall be reported in writing and orally immediately to the ordering physician, to the pharmacy and to the appropriate committee of the institutional facility. Entry on the patient's record shall also be made. The Director may at his discretion, make further reports of such suspected reactions to the Hospital Reporting Program of the U. S. Food and Drug Administration, to the manufacturer and to the United States Pharmacopoeia. (7-1-93)

14. Records and Reports. The Director shall maintain and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare, and at a minimum the following: (7-1-93)

a. Proofs of use. (7-1-93)

b. Reports of suspected adverse drug reactions. (7-1-93)

c. Inventories of emergency kits. (7-1-93)

d. Inventories of the pharmacy. (7-1-93)

e. Annual controlled substances inventories. (7-1-93)

f. Alcohol reports. (7-1-93)

g. Such other and further records and reports as may be required by law and these rules. (7-1-93)

256. ADMINISTRATION OF DRUGS.

01. Administration of Drugs. Drugs shall be administered at an institutional facility only upon the orders, including chart orders, of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff and by authorized licensed facility personnel in accordance with policies and procedures specified by the appropriate committee of the facility under applicable law and rules and by usual and customary standards of good medical practice. ~~(7-1-93)~~( )

02. Self-Administration of Drugs by Patients. Self-administration of drugs by patients shall be permitted only when specifically authorized by the treating or ordering physician, provided however, the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient. (7-1-93)

257. DRUGS FROM OUTSIDE SOURCES.

01. Outside Pharmacies. Whenever drugs or pharmaceutical services are obtained from outside of the institutional facility arrangements shall be made to insure that such outside pharmacist provides his services with sufficient professionalism, quality and availability to adequately protect the safety of the patients and to properly serve the needs of the facility. Such arrangements shall be made in writing and shall, at a minimum, specify that: (7-1-93)

a. The outside pharmacist is to act in the capacity of a part-time Director and therefore, subject to these rules. (7-1-93)

b. The pharmacist shall provide on-call service at all times. (7-1-93)

c. Adequate storage facilities for drugs will be provided. (7-1-93)

d. All prescription drugs in oral solid dosage form supplied to a licensed skilled nursing care facility, whether from an outside source or in-house pharmacy, shall be limited to no more than an eight (8) day supply except where USP indicates the drug shall be dispensed in the original container. Up to a thirty-four (34) day supply will be allowed if provided in "Unit Dose," as defined in Subsection 156.05 of these rules. (3-20-04)

e. All drugs in liquid form will be supplied in amounts not to exceed sixteen (16) ounces or an amount not to exceed a thirty-four (34) day supply. (3-20-04)

f. All drugs housed in long term care facilities will be labeled according to Section 159 of these rules. (8-4-94)

g. Automatic refilling of medications is prohibited, except where Unit Dose is used in a daily delivery system. Any continuation of medications must be reordered by the licensed skilled nursing care facility pursuant to a current physician's order. (7-01-94)

h. All drugs supplied shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised. (7-1-93)

02. **Centralized Prescription Processing or Filling for Immediate Need**. An outside pharmacy which provides prescription processing or filling services for an Institutional Facility which does not have an Institutional Pharmacy may outsource, pursuant to a contract, prescription processing or filling services to another pharmacy, and the other pharmacy may perform the prescription processing or filing services outsourced to it, provided that all of the following conditions are met: ( )

a. The outsourcing of prescription processing or filling services shall be only for the limited purpose of assuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the pharmacy outsourcing those services cannot provide services for the Institutional Facility on an ongoing basis. ( )

b. The outsourcing pharmacy has obtained approval from the Institutional Facility to outsource centralized prescription processing or filling services for its inpatients and residents. ( )

c. The outsourcing pharmacy provides a valid Chart Order to the pharmacy it has contracted with for the centralized prescription processing or filling services. ( )

d. The contract between the outsourcing pharmacy and the pharmacy with which it has contracted for centralized prescription processing or filling services is in writing. ( )

0~~2~~3. Patient's Own Drugs. (7-1-93)

a. Whenever patients bring drugs into an institutional facility such drugs shall not be administered unless they can be precisely identified; administration shall be pursuant to a physician's order, including chart order, only. ~~(7-1-93)~~( )

b. If such drugs are not to be administered, then the Director shall, according to procedures specified by him in writing, have them turned in to the pharmacy which shall package and seal them and return them to an adult member of the patient's immediate family or store and return them to the patient upon discharge. (7-1-93)