

Dear Senators LODGE, Broadsword & LeFavour, and
Representatives BLOCK, Nielsen & Rusche:

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

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy

(Docket No. 27-0101-0902) (Temporary and Proposed Fee).

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 11-13-09. 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 12-11-09.

_____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 26, 2009

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0902) (Temporary and Proposed Fee)

The Board of Pharmacy submits Docket No. 27-0101-0902, dealing with the practice of telepharmacy. Since this temporary and proposed rule affects fee, it is designated as a fee rule. Temporary fee rules become effective immediately only if the Governor finds that the fee is necessary to avoid immediate danger. Section 67-5226(2), Idaho Code. However, temporary rules and proposed fee rules do not stay in effect beyond the following legislative session unless approved by the Legislature. Section 67-5226(3) and 67-5224(5)(c), Idaho Code. Hereinafter, this rule will be referred to as the “fee rule.”

The Board states that the fee rule is in response to HB 306 (2009), amended chapter 17, title 54, Idaho Code, to permit the practice of telepharmacy, including the practice of telepharmacy across state lines. That law went into effect on July 1, 2009. According to the Board, the fee rule establishes the criteria for registration of drug outlets engaged in the practice of telepharmacy across state lines and the pharmacists engaged in that practice. Part of that regulation is a registration fee. The Board also states that the fee rule repeals existing rules regarding the telepharmacy pilot project.

The Governor’s justification for the temporary rule is to confer a benefit and for the protection of public health, safety or welfare. The Governor’s justification for imposing a temporary fee is to avoid the immediate danger of delaying the start of the practice of telepharmacy across state lines. The temporary rule went into effect on July 1, 2009.

According to the Board, the fee rule is authorized pursuant to section 54-1717, Idaho Code. 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. Additional authority

available to the Board includes sections 54-1723A and 37-2715, Idaho Code. Section 54-1723A requires the Board to specify the fee for the issuance of the registration to engage in the practice of telepharmacy across state lines and the procedures to be followed and the fees to be paid for renewal. 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.

The fee rule imposes a registration fee and an annual registration renewal fee of \$250. 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 fee rule. According to the Board, negotiated rulemaking was not conducted because of the need for temporary 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 21, 2009. All written comments must be delivered to the Board on or before October 28, 2009.

ANALYSIS

The Board's rules have definitions sections and subsections scattered throughout the chapter, rather than a dedicated definition section that applies to the entire rule. Given this structure, the application of definitions to the entire rule chapter or just the section in which they are found is not clear.

Section 252 of the Board's rule addresses pharmacy practice in institutions. The definitions under this section apply to "these rules." The fee rule adds three new definitions: "central pharmacy," "continuous quality improvement program," and "drug regimen review" and modifies one other: "centralized prescription processing." None of these new or modified definitions are defined in the Idaho Code pharmacy chapter. Section 252 also each central pharmacy must have a director. The director must be a pharmacist who is licensed or registered in Idaho and responsible for all activities of his respective institutional pharmacy or central pharmacy.

Section 257 of the fee rule is titled "Outsourcing," replacing the previous title, "Drugs from Outside Sources." Under the fee rule, an institutional pharmacy may outsource centralized prescription processing or filling services to a central pharmacy 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 institutional pharmacy cannot provide services on an ongoing basis, provided that certain conditions are met. Certain policies, procedures and documentation are required for each party performing or contracting for centralized prescription processing or filling services. The fee rule clarifies that when drugs, devices or other pharmacy services are obtained by an institutional facility without an institutional pharmacy from outside the institutional facility, certain arrangements must be met.

As advertised, the fee rule deletes sections 261 through 264, dealing with the telepharmacy pilot project.

A new subsection, addressing telepharmacy across state lines, has been added to section 292, regarding registration of drug outlets. Three definitions are provided in this new subsection: “institution engaged in the practice of telepharmacy across state lines,” “central order entry pharmacy” and “hospital system.” Both “central order entry pharmacy” and “hospital system” are component parts of the definition of “institution engaged in the practice of telepharmacy across state lines.” Such an institution must meet the requirements of section 54-1729, Idaho Code, for registration as a telepharmacy drug outlet across state lines. Section 292.10.

New section 294 of the fee rule addresses the registration of pharmacists to engage in the practice of telepharmacy across state lines. A pharmacist who engages in the practice of telepharmacy across state lines and who does not have an Idaho license must register with the Board, satisfy the statutory requirements mandated by section 54-1723A, Idaho Code, and pay a registration fee of \$250. Registration renewal requires meeting the same requirements and fee payment.

SUMMARY

The Department’s proposed rule change appears to be authorized under sections 54-1717, 54-1723A and 54-1753(1), Idaho Code.

cc: Idaho State Board of Pharmacy
Mark D. Johnston, Executive Director

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0902 (FEE RULE)

NOTICE OF RULEMAKING - TEMPORARY AND PROPOSED RULE

EFFECTIVE DATE: The effective date of the temporary rule is July 1, 2009.

AUTHORITY: In compliance with Sections 67-5221(1) and 67-5226, Idaho Code, notice is hereby given that this agency has adopted a temporary rule, and proposed rulemaking procedures have been initiated. The action is authorized pursuant to Section 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 21, 2009.

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 the required finding and concise statement of its supporting reasons for adopting a temporary rule and a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The proposed rules are necessary to implement provisions of House Bill No. 306, which was passed by the 2009 Idaho Legislature, signed by the Governor, and which became effective on July 1, 2009. The statute provides authorization for the practice of telepharmacy across state lines. It further provides that "institutions, as defined in the rules of board, engaged in the practice of telepharmacy across state lines" are "drug outlets" which are required to be registered by the Board of Pharmacy. The statute states that the Board "shall establish by rule . . . the criteria" which an institution engaged in the practice of telepharmacy across states "must meet to qualify for registration" as a "[t]elepharmacy drug outlet across state lines." The statute provides that out-of-state pharmacists who are not licensed to practice pharmacy in Idaho but who are licensed to practice pharmacy in another state, must be registered by the Idaho Board of Pharmacy before they can provide telepharmacy services for a patient located in Idaho. The statute states that the fee for such pharmacist registration is to be "the fee(s) specified by the board for the issuance of the registration." In contrast, the fee for registration of telepharmacy drug outlets across states lines is specified in the statute as "the same fee as those registering under subsection (2)(a)(ii) of this section," which is the institutional drug outlet registration category. The statute also adds to Chapter 17, Title 54, Idaho Code, definitions of "practice of telepharmacy" and "practice of telepharmacy across lines," which definitions each end with the phrase "as defined in the rules of the board."

The proposed rules establish the criteria for registration of drug outlets engaged in the practice of telepharmacy across state lines and of pharmacists engaged in the practice of telepharmacy across state lines. The proposed rules provide a necessary regulatory framework for the practice of telepharmacy across state lines in order to meet its statutory charge under the Idaho Pharmacy Act to promulgate regulations necessary to promote, preserve, and protect the health, safety, and welfare of the public by and through the effective control of the practice of pharmacy and of the registration of drug outlets. The proposed rules establish, as required by the new statute, a registration fee for registration of out-of-state pharmacists engaged in the practice of telepharmacy across state lines. The proposed registration fee is two hundred fifty dollars (\$250) and the proposed annual renewal fee is the same. The fee for registration of telepharmacy drug outlets across state lines is contained in the statute. The proposed rules also repeal existing rules regarding the Telepharmacy Pilot Project (Board Rules 261 through 264), which rules deal exclusively with telepharmacy solely within Idaho on a pilot basis, and amend other Board rules to provide rules applicable to both telepharmacy across state lines and telepharmacy within Idaho. The proposed rules authorize outsourcing, under certain circumstances, of "central prescription processing or filling" to a "central pharmacy" and define those terms. Registered telepharmacy drug outlets are included within the "central pharmacy" definition. The proposed rules establish the criteria to be met in order to outsource central prescription processing or filling. The section of the rules regarding registration of telepharmacy drug outlets across state lines includes definitions of "institution engaged in the practice of telepharmacy across state lines," "central order entry pharmacy," and "hospital system."

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(a) and (c), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons:

Temporary and proposed status is sought for the rule change. Since the statute went into effect July 1, 2009, and since the statute in several places alludes to board rulemaking regarding several specific subjects, temporary status confers a benefit in that the practice of telepharmacy across state lines can begin immediately within an articulated regulatory context. That not only confers a benefit on those entities providing and receiving telepharmacy services across state lines services and on the patients of the receiving entities, but it results in protection of the public health, safety, or welfare by allowing the practice of telepharmacy across state lines to begin in Idaho with appropriate regulatory oversight having been established from the outset. Justification for temporary status for the pharmacist registration fee portion of the rule is provided below.

FEE SUMMARY: Pursuant to Section 67-5226(2), Idaho Code, the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein:

Temporary status regarding the imposition of the fee to be paid by out-of-state pharmacists who must be registered by the Board in order to provide telepharmacy across state lines services to a patient in Idaho would avoid the immediate danger of delaying the start of the practice of telepharmacy across state lines. No pharmacist who is not licensed to practice pharmacy within the state of Idaho may engage in the practice of telepharmacy across state lines unless registered by the Board pursuant to the terms of Section 54-1723A, Idaho Code. The statute provides that in addition to the mandatory requirements in subsection (2)(a)(b) and (d) of the foregoing Section, the applicant "shall. . .(c) Pay the fee(s) specified by the board for the issuance of the registration. . ." The use of the word "shall" in a statute indicates a mandatory act. Additionally, Section 54-1729(2)(b), Idaho Code, requires that all employees or personnel of a telepharmacy drug outlet across state lines "be registered by the board pursuant to section 54-1723A, Idaho Code." An institution engaged in the practice of telepharmacy across state lines must be registered by the Board as a telepharmacy drug outlet across state lines. Section 54-1729(5), Idaho Code, however, specifies the exact registration fee to be paid for registration by an institution applying for registration as a telepharmacy. Thus, there is the incongruity of the drug outlet registration fee being fixed by statute, the pharmacist employees of such drug outlets being mandatorily required to obtain registration in order to engage in the practice of telepharmacy across state lines, and the registrant being mandatorily required as a condition of obtaining registration to "pay the fee(s) specified by the board for issuance of the registration." That incongruity creates the danger of potentially delaying the operation of telepharmacy drug outlets across state lines since the nature of the statutory framework is such that they can only provide telepharmacy services into Idaho through a pharmacist who is either licensed by the Board to practice pharmacy in Idaho or who is licensed in another state and registered by the Board in Idaho to practice telepharmacy across state lines. Permitting the pharmacist registration fee to proceed as both a temporary and proposed rule avoids the danger that the effective operation of telepharmacy across state lines would be delayed until the legislature could approve, amend, or modify by concurrent resolution a fee rule. Delay of full implementation of the statute also carries a risk of potential danger to public health, safety, or welfare in that institutions within Idaho having legitimate patient care needs which could be serviced by outsourcing certain pharmacy services to a telepharmacy drug outlet across state lines could be effectively delayed in obtaining such care for several months.

Pursuant to Section 54-1723A, the fee for registration to engage in the practice of telepharmacy across state lines will be two hundred fifty dollars (\$250) and the annual registration renewal fee will be two hundred fifty dollars (\$250).

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: NA

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the need for temporary 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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
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THE FOLLOWING IS THE TEMPORARY AND PROPOSED TEXT FOR DOCKET NO. 27-0101-0902

252. PHARMACY PRACTICE IN INSTITUTIONS.

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

a. Institutional Facility is a hospital, skilled nursing care facility, intermediate care facility, extended care facility, long-term care facility, and any other such 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 licensed practitioners of the healing arts engage in private practice. (5-8-09)

b. Long-Term Care Facility is a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients. (5-8-09)

c. Institutional Pharmacy is the portion of an institutional facility that 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 that shall be registered with the Board pursuant Title 54, Chapter 17, Idaho Code. (5-8-09)

d. Centralized Prescription Filling is the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order. (5-8-09)

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 or to perform processing functions such as dispensing and drug regimen review. (~~5-8-09~~)(7-1-09)T

f. 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: (5-8-09)

i. The full name of the patient; (5-8-09)

ii. Date of issuance; (5-8-09)

iii. Name, strength, and dosage form of the drug prescribed; (5-8-09)

- iv. Directions for use; and (5-8-09)
- 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. (5-8-09)
- g. Prepackaging is 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. (5-8-09)
- h. Central Pharmacy is defined as a pharmacy within the state of Idaho or a registered telepharmacy drug outlet across state lines to which centralized prescription processing or filling services have been outsourced pursuant to these rules. (7-1-09)T
- i. Continuous Quality Improvement Program is defined as a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. (7-1-09)T
- i. Drug Regimen Review is defined as including, but is not limited to, the following activities: (7-1-09)T
- i. Evaluation of the prescription drug order and patient records for known allergies; (7-1-09)T
- ii. Rational therapy contraindications; (7-1-09)T
- iii. Reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors; (7-1-09)T
- iv. Reasonable directions for use; (7-1-09)T
- v. Potential or actual adverse drug reactions; (7-1-09)T
- vi. Drug-drug interactions; (7-1-09)T
- vii. Drug-food interactions; (7-1-09)T
- viii. Drug-disease contraindications; (7-1-09)T
- ix. Therapeutic duplication; (7-1-09)T
- x. Proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and (7-1-09)T
- xi. Abuse or misuse. (7-1-09)T
- 02. Purpose.** Pursuant to Section 54-1703, Idaho Code, these rules implement the provisions of the Idaho Pharmacy Act concerning registration of facilities as specified in Section 54-1729, Idaho Code. (7-1-93)
- 03. Applicability.** These rules apply to all institutions and institutional pharmacies as defined in these rules. (5-8-09)
- 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 that satisfy the provisions of Section 54-1729, Idaho Code, and Subsection 251.05 through Section 259 of these rules. (7-1-93)
- 05. Directors of Institutional Pharmacy.** Each institutional pharmacy ~~shall~~ and each central pharmacy

~~must~~ be directed by a pharmacist (hereinafter referred to as “the director”) who is licensed ~~to engage in the practice of pharmacy or registered~~ in this state and who is knowledgeable in, and thoroughly familiar with the specialized functions of institutional pharmacies. ~~He shall~~ Each director will be responsible for all activities of ~~the~~ his respective institutional pharmacy ~~or central pharmacy~~ and for meeting the requirements of ~~the Idaho Pharmacy Act and these rules~~ state and federal law and regulations. (7-1-93)(7-1-09)T

06. Supportive Personnel. The director of an institutional pharmacy shall be assisted by a sufficient number of additional licensed pharmacists and ancillary personnel as may be required to operate the 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 technical personnel. (7-1-93)

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

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

07. Supervision by Director. All activities and operations of an 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 licensed pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients. (7-1-93)

09. Pharmacist Absence. During times that an institutional pharmacy is anticipated to be unattended by a licensed pharmacist, the director shall make arrangements in advance for the provision of drugs to the medical staff and other authorized personnel of the institutional facility. (7-1-93)

10. Access to Pharmacy. Only one (1) supervisory, registered nurse in any eight-hour (8) shift may be allowed access to the pharmacy and may remove drugs there from. (7-1-93)

11. Designated Nurse. The supervisory 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 recordkeeping and other required procedures. 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 the name and strength of the drug, the amount, the date and time, and signature of the nurse; and (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)

(BREAK IN CONTINUITY OF SECTIONS)

257. ~~DRUGS FROM OUTSIDE SOURCES~~ OUTSOURCING.

01. Institutional Pharmacies. An institutional pharmacy may outsource centralized prescription processing or filling services to a central pharmacy 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 institutional pharmacy cannot provide services on an ongoing basis, provided that the institutional pharmacy: (7-1-09)T

a. Has obtained approval from the institutional facility to outsource centralized prescription processing or filling services for its inpatients and residents; (7-1-09)T

b. Has a written contract with the central pharmacy outlining the services to be provided by the central pharmacy and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; (7-1-09)T

c. Provides a valid chart order to the central pharmacy it has contracted with for the centralized prescription processing or filling services; and (7-1-09)T

d. Shares a common electronic file or has appropriate technology to allow access by the central pharmacy to sufficient information necessary or required to fill or refill a prescription order. (7-1-09)T

02. Policies, Procedures, and Documentation for Institutional Pharmacies and Central Pharmacies. Each party performing or contracting for centralized prescription processing or filling services under Subsection 257.01 of these rules must: (7-1-09)T

a. Maintain a policies and procedures manual and documentation that implementation of such policies and procedures is occurring. The manual and documentation must include, but are not limited to, the following: (7-1-09)T

i. A copy of the outsourcing approval required under Paragraph 257.01.a. of these rules; (7-1-09)T

ii. A copy of the contract required under Paragraph 257.01.b. of these rules; (7-1-09)T

iii. The maintenance of appropriate records to identify the pharmacists providing centralized prescription processing or filling services; (7-1-09)T

iv. The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process; (7-1-09)T

v. The provision of adequate security to protect the privacy of protected health information;(7-1-09)T

vi. The protocol for accessing prescription drugs in the institutional pharmacy outsourcing centralized prescription processing or filling services and for maintaining the security of such drugs; (7-1-09)T

vii. The protocol to assure that the central pharmacy maintains sufficient Board licensed or registered pharmacists to meet the centralized processing or filling needs of the institutional facility outsourcing such services to the central pharmacy; (7-1-09)T

viii. Identification of the director of the central pharmacy and of the institutional pharmacy contracting with the central pharmacy; and (7-1-09)T

ix. The maintenance of a continuous quality improvement program for centralized processing or filling services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. (7-1-09)T

b. Implementation documentation must be retained for a period of two (2) years. (7-1-09)T

c. Make the policy and procedures manual and implementation documentation available to the Board for review upon request. (7-1-09)T

043. ~~Outside Pharmacies~~ Institutional Facilities. Whenever an institutional facility without an institutional pharmacy obtains drugs, devices, or ~~pharmaceutical~~ other pharmacy services ~~are obtained~~ from outside

of the institutional facility, arrangements ~~shall~~ **must** be made to ensure 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. The arrangements shall be made in writing and shall, at a minimum, specify that: ~~(7-1-93)~~(7-1-09)T

- a. The outside pharmacist is to act in the capacity of a part-time director and therefore, is 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 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; and (7-01-94)
- h. All drugs supplied shall be labeled so as to ensure that recalls can be effected and that proper control and supervision of the drugs may be exercised. (7-1-93)

~~024.~~ **Centralized Prescription Processing or Filling for Immediate Need Limited Outsourcing by Outside Pharmacy.** An outside pharmacy that provides prescription processing or filling services for an institutional facility ~~which that~~ 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 filling services outsourced to it, if all of the following conditions are met: ~~(5-8-09)~~(7-1-09)T

- a. The outsourcing of prescription processing or filling services shall be only for the limited purpose of ensuring 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; (5-8-09)
- b. The outsourcing pharmacy has obtained approval from the Institutional Facility to outsource centralized prescription processing or filling services for its inpatients and residents; (5-8-09)
- c. The outsourcing pharmacy provides a valid chart order to the pharmacy it has contracted with for the centralized prescription processing or filling services; and (5-8-09)
- 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. (5-8-09)

~~035.~~ **Patient's Own Drugs.** (7-1-93)

- a. Whenever patients bring drugs into an institutional facility, the drugs shall not be administered unless they can be precisely identified and only pursuant to a physician's order, including chart order. (5-8-09)
- b. If the patient's drugs are not to be administered, then the director shall, according to procedures specified in writing, have the patient's drugs turned in to the pharmacy, which shall package, seal, 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)

(BREAK IN CONTINUITY OF SECTIONS)

~~261. TELEPHARMACY PILOT PROJECT.~~

~~The Board, through its executive director, may authorize specific institutional facilities and the institutional pharmacies located therein to participate in a telepharmacy program. The following rules shall apply to institutions so authorized by the Board for the telepharmacy practiced in the institution. The purpose of the Telepharmacy Pilot Project is to allow the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care. During the pilot project phase of the telepharmacy program, designation to participate in the telepharmacy program shall be at the discretion of the Board and the executive director.~~ (4-6-05)

~~262. DEFINITIONS.~~

~~01. **Central Pharmacy.** An institutional pharmacy authorized by the Board to participate in a telepharmacy program.~~ (4-6-05)

~~02. **Consulting Pharmacists.** Pharmacists employed at a central pharmacy who provide pharmaceutical care to patients at a rural institutional facility.~~ (4-6-05)

~~03. **Rural Institutional Facility.** An institutional facility authorized by the Board to participate in a telepharmacy program. Rural institutional facilities are those facilities federally designated as critical access hospitals or other facilities operating in a health professional shortage area and that are unable to otherwise obtain pharmaceutical care on a timely basis twenty-four (24) hours per day.~~ (4-6-05)

~~04. **Rural Institutional Pharmacy.** The institutional pharmacy located within a rural institutional facility.~~ (4-6-05)

~~05. **Telepharmacy Program.** The pilot project adopted by the Board to allow selected central pharmacies and selected rural institutional facilities to engage in the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care.~~ (4-6-05)

~~263. CONTRACT FOR TELEPHARMACY PROGRAM.~~

~~A central pharmacy may contract with a rural institutional facility for operation of a telepharmacy program as specified herein.~~ (4-6-05)

~~01. **Contract Matters.** The contract shall address the following matters:~~ (4-6-05)

~~a. Identify the director of pharmacy of the central pharmacy and the director of pharmacy of the rural institutional pharmacy and provide for notice to the parties and to the Board in the event of a change in either director.~~ (4-6-05)

~~b. Contain a description of the telepharmacy services to be performed by the central pharmacy for the rural institutional pharmacy, including:~~ (4-6-05)

~~i. Protocols for communication of orders for prescription drugs from the practitioners at the rural institutional pharmacy to the pharmacists at the central pharmacy.~~ (4-6-05)

~~ii. Protocols for the central pharmacy to accomplish dispensing of prescription drugs at the rural institutional facility and to ensure that the central pharmacy has sufficient consulting pharmacists and support staff to meet the pharmacy needs of the institutional facility where the central pharmacy is located as well as performing the pharmacy functions for the rural institutional pharmacy as are contemplated under the contract.~~ (4-6-05)

~~iii. A description of the access to prescription drugs in the rural institutional pharmacy under the program and protocol for maintaining the security of prescription drugs in the rural institutional pharmacy. (4-6-05)~~

~~iv. Contain a provision for the orderly transition of pharmaceutical services for the rural institutional pharmacy in the event the central pharmacy elects to terminate its participation in the telepharmacy program, such transition to include an adequate time for the rural institutional pharmacy to locate appropriate pharmaceutical services from another source. (4-6-05)~~

~~v. The term of the contract shall not exceed two (2) years and shall be subject to the right of the Board and its executive director to conduct an annual review of the operations under the contract and of the telepharmacy program. (4-6-05)~~

~~02. **Additional Contract Matters.** The contract may address additional matters regarding the Telepharmacy Program between the central pharmacy and the rural institutional facility. (4-6-05)~~

~~03. **Contract Approval.** The contract must be approved by the executive director of the Board prior to the commencement of telepharmacy services between the central pharmacy and the rural institutional facility. In reviewing the contract, the executive director shall evaluate the proposed terms in the light of: (4-6-05)~~

~~a. Promoting, preserving, and protecting the health, safety, and welfare of the public; (4-6-05)~~

~~b. Maintaining appropriate professional standards for the practice of pharmacy; and (4-6-05)~~

~~c. Maintaining appropriate safeguards for the protection of prescription drug inventories, especially controlled substance inventories, at the Rural Institutional Pharmacy. (4-6-05)~~

~~**264. SPECIAL RULES FOR DIVISION OF RESPONSIBILITY FOR TELEPHARMACY.**~~

~~Notwithstanding anything in these rules to the contrary, for rural institutional pharmacies and central pharmacies, and the pharmacists practicing under an approved contract for telepharmacy services, the following rules shall apply. (4-6-05)~~

~~01. **Responsibility of Director of Central Pharmacy.** The director of pharmacy of the central pharmacy shall be responsible for all telepharmacy services performed by the central pharmacy under the approved contract and for meeting the requirements of the Idaho Pharmacy Act and these rules with respect to such services. The telepharmacy activities and operations performed by the central pharmacy under the approved contract and the ancillary personnel of the central pharmacy engaged in such activities and operations shall be personally and directly supervised by the director of pharmacy in the same fashion as all other activities and operations at the central pharmacy. (4-6-05)~~

~~02. **Responsibility of Director of Rural Institutional Pharmacy.** The director of pharmacy of the rural institutional pharmacy shall remain responsible for all other aspects of the rural institutional pharmacy but shall not be responsible for the services performed by the central pharmacy under the approved contract. Where ancillary personnel are directed or supervised in telepharmacy activities by the central pharmacy, responsibility for such direction and supervision shall lie with the central pharmacy and the director thereof. (4-6-05)~~

~~**261. -- 264. (RESERVED).**~~

(BREAK IN CONTINUITY OF SECTIONS)

292. REGISTRATION, DRUG OUTLET.

01. Annual Renewal of Registration of Drug Outlet. (7-1-93)

a. Annually each drug outlet shall renew its registration no later than July 1 on a form provided by the Board and accompanied by the required fee. (7-1-93)

b. Each facility may be inspected by an inspector of the Board to ascertain that proper procedures are being carried out in regard to distribution of drugs. (7-1-93)

02. Retail Drug Outlet. (7-1-93)

a. A Retail Pharmacy Drug Outlet is a community pharmacy or any other pharmacy managed by an Idaho licensed pharmacist. (7-1-93)

b. A Retail Non-Pharmacy Drug Outlet includes any grocery store, bar, hotel, department store, vending machine, etc., not registered as a pharmacy that sells non-legend drugs, devices, or medical supplies to be sold at retail. (7-1-93)

03. Registrations and Renewals of Retail Non-Pharmacy Drug Outlet. For the issuing of registrations and renewals required by Section 54-1729, Idaho Code, the fee for each retail non-pharmacy drug outlet registration shall be determined as follows: (7-1-93)

a. "B" registration for those stocking not more than fifty (50) drug items; (8-4-94)

b. "A" registration for those stocking more than fifty (50) drug items; and (7-1-93)

c. "V" registration for vending machines, annual fee of five dollars (\$5). (8-4-94)

d. Reinstatement of a non-pharmacy registration shall be a minimum of five dollars (\$5) or one-half (1/2) the annual fee. (7-1-93)

04. Institutional Pharmacy Outlet. A hospital pharmacy, nursing home pharmacy, state institution pharmacy, and any other institutional outlet having a pharmacy within the facility. (7-1-93)

05. Institutional Non-Pharmacy Drug Outlet. A hospital, nursing home, state institution, shelter home, convalescent home, extended care facility, drug abuse treatment center, family planning clinic, and any other outlet not having a pharmacy within the facility. (7-1-93)

06. Manufacturing Drug Outlet. A manufacturer manufacturing pharmaceuticals within the state, or a manufacturer located outside the state but doing business within the state of Idaho. (7-1-93)

07. Wholesale Drug Outlet. A company located within the state or outside the state but doing business within the state of Idaho. (7-1-93)

08. Vending Machines. Machines used for non-prescription drugs not otherwise restricted for over-the-counter sale will be considered a separate drug outlet and must be registered with the Board. (7-1-93)

a. Application for registration must be made on forms provided by the Board, accompanied by a reasonable registration fee for each machine that shall have a registration number issued by the Board. (7-1-93)

b. Registration must be renewed annually on or before June 30. (7-1-93)

c. Drugs and medical supplies stored in vending machines are subject to inspection by the Board upon reasonable notice. (7-1-93)

09. Durable Medical Equipment (DME) Outlet. (7-1-98)

a. All entities holding for sale legend or non-legend devices to be sold at retail or wholesale must be registered with the Board. Said legend devices may only be sold or delivered at retail upon the lawful order of a practitioner. DME outlets may hold non-legend drugs for sale. (7-1-98)

b. Registered DME outlets may hold for sale at retail only upon the order of a practitioner the following legend drugs: (7-1-98)

- i. Pure oxygen for human application; (7-1-98)
- ii. Nitrous oxide; (7-1-98)
- iii. Sterile sodium chloride; and (7-1-98)
- iv. Sterile water for injection. (7-1-98)

10. Telepharmacy Drug Outlet Across State Lines. (7-1-09)T

a. “Institution engaged in the practice of telepharmacy across state lines” means an out-of-state hospital with an institutional pharmacy licensed or registered in another state, or a central order entry pharmacy licensed or registered in another state and that is part of a hospital system. (7-1-09)T

b. “Central order entry pharmacy” means an out-of-state pharmacy that processes information related to the practice of pharmacy, that engages solely in centralized prescription processing but from which drugs are not dispensed, and that is physically located outside the institutional pharmacy of a hospital. (7-1-09)T

c. “Hospital system” means one (1) or more hospitals under common ownership, where at least one (1) of the hospitals has within it a licensed or registered institutional pharmacy. A hospital system may also include, under the same common ownership, one (1) or more licensed or registered central order entry pharmacies. (7-1-09)T

d. For registration as a telepharmacy drug outlet across state lines, an institution engaged in the practice of telepharmacy across state lines must satisfy the requirements of Section 54-1729, Idaho Code. (7-1-09)T

101. Registration Issued at Specific Location. A registration will be issued to an applicant at a specific location and is not transferable as to person or place. (7-1-93)

(BREAK IN CONTINUITY OF SECTIONS)

294. REGISTRATION OF PHARMACISTS TO ENGAGE IN THE PRACTICE OF TELEPHARMACY ACROSS STATE LINES.

01. Registration. To engage in the practice of telepharmacy across state lines, a pharmacist who is not licensed to practice pharmacy within the state of Idaho must be registered by the Board. (7-1-09)T

02. Requirements and Registration Fee. In order to be registered to engage in the practice of telepharmacy across state lines, the pharmacist must satisfy all the requirements of Section 54-1723A, Idaho Code, and pay a registration fee of two hundred fifty dollars (\$250). (7-1-09)T

03. Renewal and Renewal Fee. The renewal of registration to engage in the practice of telepharmacy across state lines will be as specified in Section 54-1723A(5), Idaho Code, and the annual renewal fee shall be two hundred fifty dollars (\$250). (7-1-09)T

2945. -- 320. (RESERVED).