

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

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. 27-0101-0807).

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
10-24-08. 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 11-21-08.

_____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 6, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0807 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0807 (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 has been previously approved by the Legislature in both 2007 and 2008 as a temporary rule. The proposed rule, dealing with remote pharmacy dispensing pilot project, seeks to make that temporary rule permanent with the following modifications:

1. Substitute the phrase “pharmacist-in-charge” for “responsible pharmacist”;
2. Require that the operating agreement include the description of procedures detailing the security and accounting of returned, discarded or unused medications in accordance with state and federal laws, rules and regulations;
3. Permit access to the pharmacy’s remote dispensing machine by certain persons other than a licensed pharmacist in situations specifically detailed in the operating agreement approved by the Board;

4. Delete the provision regarding wasted, discarded or unused medication in view of the requirement that the operating agreement include procedures dealing with the security and accounting of returned, discarded or unused medications;
5. Require that the operating agreement include other provisions determined by the Board to be necessary to protect the public health, safety and welfare; and
6. Make technical corrections.

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

The Board seeks to establish a pilot project using remote dispensing machines (RDMs) to assist in the dispensing of pharmaceuticals at remote locations away from the pharmacy. The pilot project envisions placing an RDM, essentially a large container stocked with pharmaceuticals, at a remote clinic that does not have ready access to a pharmacy. The patient would bring a prescription to the clinic where a technician would forward the prescription information to the pharmacist. After the prescription has been reviewed by the pharmacist, the pharmacist is able to remotely operate the RDM so that the prescribed medication is released to the patient. A two-way video and audio system allows the patient to consult with the pharmacist.

The definition section of the rules has been augmented by the definition of "Board," meaning the Idaho Board of Pharmacy. Section 010.01.

Section 265 states the purpose of the pilot program is "to allow the provision of pharmaceutical care through the use of telecommunications and Remote Dispensing Machines (RDM) to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care." Designation to participate in the pilot project phase of the program is at the discretion of the Board and the Executive Director.

Each RDM must be registered with the Board as a Pilot Remote Pharmacy and must be located at medical care facilities operating in areas otherwise unable to obtain pharmaceutical care on a timely basis. The prescription orders are to be reviewed by a pharmacist before release to the patient. Policies and procedures established by the Responsible Pharmacy operating the RDMs must meet all applicable state and federal law, rules and regulations. Section 267.01.

Before a Remote Pharmacy can be registered, its Pharmacist in Charge and the Board's Executive Director must enter into an Operating Memorandum which must include: detailed

operating protocols, the RDM's operating specifications, an accurate scale drawing of the facility where the RDM will be located, a description of the training required for personnel who will access the facility where the RDM is located with a requirement for documentation of the training and continuing education, a description of the procedures from ensuring the RDM is in good working order and is accurately dispensing the drugs while maintaining appropriate record-keeping and security safeguards, an ongoing quality assurance program, such other terms and conditions as the Board's Executive Director deems reasonably necessary to ensure the health, safety and welfare of the public, and a description of the procedures detailing the security and accounting of returned, discarded or unused medications with existing law. Section 267.02.

The legally compliant Operating Memorandum governs all operations of the facility with regards to the practice of pharmacy and may identify specific rules of the Board which are not applicable to the facility's operation or which particular applications have been modified due to the specific nature of the facility's operations. Section 267.03.

In case of a dispute between the Board's Executive Director and the Pharmacist in Charge over the Operating Memorandum, the Board may be petitioned for a determination, which shall be final. The Operating Memorandum may be amended by written agreement between the Executive Director and the Pharmacist in Charge or by order of the Board, either on its own motion or upon petition. Section 267.04.

The Pharmacist-in-Charge is responsible for all aspects of the operation of the Remote Pharmacy and must ensure that the RDM is accurately and properly stocked. Section 268. At all times the system is being operated, either a licensed pharmacist or a registered technician must be present at the facility and attending the operations, section 269.01, and must be in two-way audio and video hookup between the Responsible Pharmacy and the Pilot Remote Pharmacy while the Remote Pharmacy is being operated, section 269.02. Specified electronic records of all events involving the contents of the RDM must be kept for three (3) years. Section 269.03.

Only a licensed pharmacist may have access to and stock the RDM, unless specifically detailed in the approved Operating Memorandum. Sections 269.04 and .05. All containers stored in the RDM must be properly labeled pursuant to applicable law. Section 269.06. Controlled substances must meet all state and federal requirements. Section 269.07. A licensed pharmacist must be available to provide oral counseling to the patient at the time of dispensing via two-way audio and video hookup. Section 269.08. The RDM must be clearly marked with the Responsible Pharmacy's and the Pharmacist-in-Charge's contact information. Section 269.10.

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. 27-0101-0807

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:

These rules were originally published as temporary on August 2, 2006 in the Administrative Bulletin, Vol. 06-8, pages 74 through 78 (Docket No. 27-0101-0601); approved and extended by the 2007 Legislature by SCR 120; and extended by the 2008 Legislature by SCR 139. Based upon the passage of time and experience required by the Board with the pilot program, the Board proposes to make permanent the temporary rules regarding the Remote Dispensing Pilot Project. The proposed rules make permanent the temporary rules regarding the remote pharmacy dispensing pilot project and amends those rules to substitute the phrase "pharmacist-in-charge" for "responsible pharmacist;" to require that the operating agreement include the description of procedures detailing the security and accounting of returned, discarded, or unused medications in accordance with state and federal laws, rules, and regulations; to permit access to the pharmacy's remote dispensing machine by certain persons other than a licensed pharmacist in situations specifically detailed in the operating agreement approved by the Board; to delete the provision regarding wasted, discarded, or unused medications in view of the requirement that the operating agreement include procedures dealing with the security and accounting of returned, discarded, or unused medications; to renumber paragraphs due to the foregoing deletion; and to require that the operating agreement include other provisions determined by the Board to be necessary to protect the public health, safety, and welfare.

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. 27-0101-0807

01. Board. Idaho Board of Pharmacy. ()

042. Pharmacist Extern. Any person enrolled in an approved college of pharmacy who has not received his first professional degree in pharmacy, and who is obtaining experience under the supervision of a pharmacist preceptor. (6-30-95)

023. Pharmacist Intern. Any person who has successfully completed a course of study at an accredited college or school of pharmacy and received the first professional degree in pharmacy, and who is obtaining practical experience under the supervision of a pharmacist preceptor. (6-30-95)

034. Preceptor. A licensed pharmacist in good standing engaged in the practice of pharmacy at a registered training site and directly responsible in supervising the training of a pharmacist extern or intern. The preceptor shall be responsible for: (6-30-95)

a. Personally providing the extern or intern with training experience which in his judgment will increase the extern or intern's proficiency; and (6-30-95)

b. Reporting to the Board upon request, the progress of any pharmacy extern or intern under his supervision; and (6-30-95)

c. Certifying the extern or intern's experience affidavits when the extern or intern leaves his supervision. (6-30-95)

045. Ratios. A ratio of one (1) pharmacist preceptor to one (1) extern or intern will be required for dispensing functions. (6-30-95)

(BREAK IN CONTINUITY OF SECTIONS)

265. REMOTE DISPENSING PILOT PROJECT.

The Board, through its Executive Director, may authorize specific pharmacies and the pharmacists practicing therein to participate in a Remote Dispensing Pilot Program. The following rules shall apply to pharmacies so authorized by the Board for conducting pharmacy through a Remote Dispensing Program. The purpose of the Remote Dispensing Pilot Program is to allow the provision of pharmaceutical care through the use of telecommunications and Remote Dispensing Machines (RDM) to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care. During the pilot project phase of the Remote Dispensing Pilot Program, designation to participate in the Remote Dispensing Pilot Program shall be at the discretion of the Board and the Executive Director. ()

2656. — 290. (RESERVED).

267. REMOTE PHARMACY REGISTRATION - OPERATING MEMORANDUM.

01. Registration. During the pilot project phase of the Remote Dispensing Pilot Project, each Remote Pharmacy shall be registered with the Board as a Pilot Remote Pharmacy. Pilot Remote Pharmacies will only be approved for operating in medical care facilities operating in areas otherwise unable to obtain pharmaceutical care on a timely basis. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws, rules, and regulations. ()

02. Operating Memorandum. Prior to issuance of a registration for a Pilot Remote Pharmacy, the Responsible Pharmacy, acting through its Pharmacist-In-Charge, and the Board, acting through its Executive Director, shall enter into an operating memorandum which shall contain: ()

a. The operating protocols applicable to the Pilot Remote Pharmacy and which shall include written policies and procedures that: ()

i. Ensure safety, accuracy, security, and patient confidentiality; ()

ii. Define access to the RDM and to medications contained within or associated with the RDM, including but not limited to policies that assign, discontinue, or change access to the RDM and medications; and ()

iii. Ensure that access to the medications complies with state and federal laws and regulations. ()

b. A complete description of the RDM including the operating specifications therefore. ()

c. An accurate scale drawing of the facility where the Automated Pharmacy System, including its RDM, will be located showing the layout of the location of the RDM, the facilities for the operating pharmacy technician operating the system, the location of a patient counseling area, all access points to the system and the RDM. ()

d. A description of the training required for personnel who will access the Automated Pharmacy System (including the RDM) to ensure the competence and ability of all personnel who operate any component of the Automated Pharmacy System and a requirement that adequate documentation of training and continuing education be kept both in the Responsible Pharmacy and at the Pilot Remote Pharmacy, readily available for inspection by the Board. ()

e. A description of the procedures for ensuring that the RDM is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards. ()

f. An ongoing quality assurance program that monitors performance of the Automated Pharmacy System, including the RDM, and the personnel who access it. ()

g. Such other terms and conditions of operations as the Executive Director deems are reasonably necessary to ensure the health, safety, and welfare of the public with respect to the operations of the Pilot Remote Pharmacy. ()

h. A description of the procedures detailing the security and accounting of returned, discarded, or unused medications with existing state and federal laws, rules, and regulations. ()

03. Pilot Remote Pharmacy Operations. The Operating Memorandum shall govern (in conjunction with all applicable laws, rules, and regulations) the operations of the Pilot Remote Pharmacy with respect to all aspects of the practice of pharmacy at the Pilot Remote Pharmacy. The Operating Memorandum may identify specific rules of the Board which are not applicable to the operation of the Pilot Remote Pharmacy or for which particular applications are modified due to the specific nature of the operations at the Pilot Remote Pharmacy, provided however, the Operating Agreement may not waive or modify application of Federal laws or regulations, or state statutes governing the practice of pharmacy. ()

04. Dispute Resolution. In the event of a dispute between the Pharmacist-In-Charge and the Executive Director with respect to specific terms or conditions of the Operating Memorandum, either may petition the Board for a determination, which determination by the Board shall be final. The Operating Memorandum may be amended by agreement between the Pharmacist-In-Charge and the Executive Director. Any such amendment shall be in writing and shall be appended to the original Operating Memorandum. In addition, the Operating Agreement may be amended by order of the Board upon the petition of either the Pharmacist-In-Charge or the Executive Director to the

Board, or upon the Board's own motion. Any such Board order shall be appended to the original Operating Memorandum. ()

268. PHARMACIST-IN-CHARGE.

01. Responsibilities. The Pharmacist-In-Charge shall be responsible for all aspects of the operation of the Pilot Remote Pharmacy including safety, accuracy, security, and patient confidentiality. ()

02. Product Supply. The Pharmacist-In-Charge shall ensure that the RDM is stocked accurately and in accordance with the established, written policies and procedures. A pharmacist must check the accuracy of the product supplied for stocking the machine. ()

269. DRUG DELIVERY AND CONTROL.

01. Licensed Pharmacist Present. At all times the Automated Pharmacy System is being operated, there shall be a pharmacist licensed in the state of Idaho, or a technician registered in the state of Idaho, present at the Pilot Remote Pharmacy and attending to such operations. ()

02. Communication. At all times the Automated Pharmacy System is being operated, there shall be a pharmacist licensed in the state of Idaho available at the Responsible Pharmacy for immediate communication through a two-way audio and video hookup between the Responsible Pharmacy and the Pilot Remote Pharmacy. ()

03. Electronic Recording. All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the Responsible Pharmacy for a minimum of three (3) years and must be readily available to the Board. Such records are in addition to any records required under other statutes, regulations, or rules, and shall be available for inspection by the Board in the same fashion as other required pharmacy records, and shall include: ()

- a. Identity of RDM accessed;** ()
- b. Identification of the individual accessing the RDM;** ()
- c. Type of transaction;** ()
- d. Date and time of transaction;** ()
- e. Name, strength, dosage form, and quantity of the drug accessed;** ()
- f. Name of the patient for whom the drug was ordered;** ()
- g. Name of the prescribing practitioner; and** ()
- h. Such additional information as the Pharmacist-In-Charge may deem necessary.** ()

04. Access to RDM. Only an Idaho licensed pharmacist may have access to the RDM, unless specifically detailed in the approved operating memorandum. ()

05. Stocking Medications. Only an Idaho licensed pharmacist may stock medications in the RDM unless specifically detailed in the approved Operating Memorandum. ()

06. Packaging and Labeling. All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws, rules, and regulations. ()

07. Handling Controlled Substances. All aspects of handling controlled substances shall meet the requirements of all state and federal laws, rules, and regulations. ()

08. Counseling. Oral counseling shall be provided by a pharmacist licensed in Idaho at the time of dispensing by a two-way audio and video hookup between the Responsible Pharmacy and the Pilot Remote Pharmacy. ()

09. RDM Identification. The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge. ()

270. -- 290. (RESERVED).