Dear Senators LODGE, Broadsword, Bock, and
Representatives MCGEACHIN, Bilbao, 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. 27-0101-1201);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1202);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1203);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1204);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Fee Rule) (Docket No. 27-0101-1205).

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 10/15/2012. 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 11/13/2012.

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 334-4845, or send a written request to the address on the memorandum attached below.

Legislative Services Office
Idaho State Legislature

Jeff Youtz
Director

Serving Idaho's Citizen Legislature

MEMORANDUM

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

FROM: Legislative Research Analyst - Ryan Bush

DATE: September 25, 2012

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1201)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1202)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1203)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1204)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Fee Rule) (Docket No. 27-0101-1205)

(1) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1201)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1201). The Board states that the proposed rulemaking is to clarify the practice limitations of pharmacists and members of a committee, to clarify that a pharmacist may order lab tests and substitute drug products in certain instances, and to require that a pharmacist be on a skilled nursing facility's quality assurance and assessment committee.

The Board states that negotiated rulemaking was conducted and notice was published in the May 2, 2012, Idaho Administrative Bulletin, Vol. 12-5, page 82 and in the August 1, 2012, Idaho Administrative Bulletin, Vol. 12-8, page 73. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(2) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1202)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1202). The Board states that the proposed rulemaking is to provide for ease of reading and that the changes are mostly non-substantive and housekeeping in nature. Specifically, this rulemaking moves a sub-rule, clarifies dates, renames certain facilities, strikes extraneous verbiage and revises terminology.

The Board states that negotiated rulemaking was conducted and notice was published in the May 2, 2012, Idaho Administrative Bulletin, Vol. 12-5, page 82 and in the August 1, 2012, Idaho Administrative Bulletin, Vol. 12-8, page 73. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(3) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1203)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1203). The Board states that the proposed rulemaking is to clarify confusing, absent and incomplete language. Specifically, this rulemaking accomplishes the following:

(1) Revises definitions and verbiage;

(2) Adds to and revises the requirements for student pharmacist and technician-in-training registration;

(3) Adds "Pharmacist Identification" to standard prescription drug labeling;

(4) Provides that positive identification will be presumed when the filled prescription is delivered to the patient's residence;

(5) Clarifies requirements for pharmacy security, change of ownership and permanent closing;

(6) Provides that an outgoing or incoming director of an institutional pharmacy must report to the Board;

(7) Adds to and revises the requirements for outpatient drug delivery by hospital emergency rooms; and

(8) Provides for toll-free telephone service for out-of-state mail service pharmacies.

The Board states that negotiated rulemaking was conducted and notice was published in the May 2, 2012, Idaho Administrative Bulletin, Vol. 12-5, page 82 and in the August 1, 2012, Idaho Administrative Bulletin, Vol. 12-8, page 73. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(4) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1204)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-1204). The Board states that the proposed rulemaking expands the use of self-service automated dispensing and storage systems (ADS) to hospital emergency rooms. Specifically, this rulemaking accomplishes the following:

(1) Revises the minimum standards for ADS systems;

(2) Adds new minimum standards for ADS systems that are self-serving;

(3) Revises the requirements for drug returns to ADS systems;

(4) Revises the mechanism for accounting for wasted controlled substances in an ADS transaction; and

(5) Provides for the sale of non-prescription medical supplies and drugs in vending machines.

The Board states that negotiated rulemaking was conducted and notice was published in the May 2, 2012, Idaho Administrative Bulletin, Vol. 12-5, page 82 and in the August 1, 2012, Idaho Administrative Bulletin, Vol. 12-8, page 73. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(5) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Fee Rule) (Docket No. 27-0101-1205)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Fee Rule) (Docket No. 27-0101-1205). The Board states that industry and rural Idaho hospitals are asking that more forms of the practice of pharmacy be allowed by nonresidents in order to improve public safety and that this rulemaking is being proposed in response. Specifically, this rulemaking accomplishes the following:

(1) Adds to and revises definitions, including the definitions for "Centralized Pharmacy Services" and "Mail Service Pharmacy;"

(2) Provides for an initial license fee of five hundred dollars ($500) and annual renewal fee of two hundred fifty dollars ($250) for a nonresident central drug outlet;

(3) Provides for licensing and registration for pharmacists practicing into the state of Idaho and provides criteria;

(4) Removes references to telepharmacy;

(5) Provides for registration for nonresident central drug outlets and mail service pharmacies and provides criteria;

(6) Provides for independent practice for a pharmacist if not subject to centralized pharmacy service rules;

(7) Provides that a central drug outlet must have a pharmacist-in-charge or director;

(8) Provides for centralized pharmacy services and provides criteria such as training, communication and privacy; and

(9) Adds to the rules for offsite services.

The Board states that negotiated rulemaking was conducted and notice was published in the May 2, 2012, Idaho Administrative Bulletin, Vol. 12-5, page 82 and in the August 1, 2012, Idaho Administrative Bulletin, Vol. 12-8, page 73. The Board states in its cost/benefit analysis that this rulemaking is expected to increase annual income by $150,000 but that the Board will assume additional licensing, registration and investigational costs.

The proposed rule appears to be within the statutory authority granted to the Board in Sections 54-1717, 54-1720 and 54-1743, Idaho Code.

cc: Board of Pharmacy
Mark Johnston, R.Ph.

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1201

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 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 17, 2012.

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 changes are needed for ease of reading and are mostly non-substantive. The rule changes included in this proposed docket are housekeeping in nature, as that they move a sub-rule, clarify renewal dates, rename registration categories, correct punctuation, change a rule number, strike extraneous verbiage, include references to recent changes to Idaho Code, harmonize terminology, and change a title.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

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 Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 2, 2012 Idaho Administrative Bulletin, Vol. 12-5, Page 82, and in the August 1, 2012 Idaho Administrative Bulletin, Vol. 12-8, page 73, Docket No. 27-0101-1201.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 24, 2012.

DATED this 5th day of September, 2012.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Telephone: (208) 334-2356
FAX: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1201

013. WAIVERS OR VARIANCES.

01. Criteria. The Board may grant or deny, in whole or in part, a waiver of, or variance from, specified Board rules based on consideration of the following: (3-21-12)

a. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; (3-21-12)

b. The waiver or variance requested would not allow conduct specifically prohibited by, or otherwise contrary to, state or federal law; (3-21-12)

c. The granting of the waiver or variance is consistent with the Board's mandate to promote, preserve, and protect public health, safety, and welfare; and (3-21-12)

~~***d.*** *The granting of the waiver or variance will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested.~~ ~~*(3-21-12)*~~

02. Content and Filing of a Waiver or Variance Petition. A petition for waiver or variance must be submitted in writing and must include at least the following:(3-21-12)

a. The name, address, and telephone number of the petitioner; (3-21-12)

b. A specific reference to the rule or rules from which a waiver or variance is requested; (3-21-12)

c. A statement detailing the waiver or variance requested, including the precise scope and duration; (3-21-12)

d. The name, address, and telephone number of any public agency or political subdivision that also regulates the activity in question or that might be affected by the granting of the waiver or variance; and(3-21-12)

e. The name, address, and telephone number of any known person who would be adversely affected by the granting of the waiver or variance. (3-21-12)

f. A description of how the waiver or variance, if granted, will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. ( )

03. Additional Information. Prior to granting or denying the waiver or variance, the executive director may request additional information from the petitioner and may require the petitioner to appear before the Board at an upcoming Board meeting. (3-21-12)

04. Granting or Denying the Petition for Waiver or Variance. The decision to grant or deny the petition for waiver or variance will be at the discretion of the Board or, pursuant to Board authorization, its executive director based upon consideration of relevant factors. (3-21-12)

05. Prohibited Requests. A waiver or variance request that is contrary to federal law or Idaho Code or that seeks to delay or cancel an administrative deadline will not be considered or granted by the Board. (3-21-12)

06. Conditions. Waivers or variances may be granted subject to binding conditions, limitations, or restrictions determined necessary to protect the public health, safety, and welfare. (3-21-12)

07. Time Period of Waiver or Variance. Waivers or variances may be granted on a permanent or temporary basis. Temporary waivers or variances have no automatic renewal, but may be renewed if the Board finds

that sufficient grounds to allow the waiver or variance continue to exist. (3-21-12)

08. Cancellation or Modification of a Waiver or Variance. A waiver or variance granted by the Board may be cancelled or modified if the Board finds any of the following: (3-21-12)

a. The petitioner or other person who was the subject of the waiver or variance withheld or misrepresented material facts; (3-21-12)

b. The alternative means for ensuring adequate protection of public health, safety, or welfare are demonstrated to be insufficient after issuance of the waiver or variance; or (3-21-12)

c. The subject of the waiver or variance has failed to comply with the prescribed conditions, limitations, or restrictions of the waiver or variance. (3-21-12)

09. Violations. Violation of a condition, restriction, or limitation of a waiver or variance will be deemed a violation of the particular rule or rules for which the waiver or variance was granted. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

016. BOARD OF PHARMACY LICENSURE AND REGISTRATION.
The Board is responsible for the control and regulation of the practice of pharmacy in or into the state of Idaho, which includes the licensure or registration of professional, supportive, and ancillary personnel who engage in or support the practice. The Board is also responsible for the control, regulation, and registration of persons or drug outlets that manufacture, distribute, or dispense controlled substances within or into the state. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions. (3-21-12)

01. Pharmacy Practice Act Licenses and Registrations. The Board will issue or renew a license or a certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act and any additional criteria specified by these rules for the license or registration classification. Licenses and certificates of registration issued pursuant to Title 54, Chapter 17, Idaho Code, expire annually on June 30 unless an alternate expiration term or date is specifically stated in these rules. (3-21-12)

02. Idaho Controlled Substances Act Registrations. The Board will issue or renew controlled substance registrations upon application and determination that the applicant has satisfied the requirements of the Idaho Controlled Substances Act and any additional criteria specified by state or federal law applicable to applicants that manufacture, distribute, or dispense, or conduct research with, controlled substances. Registrations issued pursuant to Title 37, Chapter 27, Idaho Code, ~~*expire*~~ must be renewed annually ~~*on*~~ by June 30 for pharmacists and ~~*on*~~ by December 31 for all other registrants. ~~*(3-21-12)*~~( )

a. Unless a wholesaler, an applicant for an Idaho controlled substance registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances and, unless a pharmacist or certified euthanasia technician, a valid federal DEA registration. If a required license or registration is cancelled or otherwise invalidated by the issuing agency, the Idaho controlled substance registration will be correspondingly cancelled. (3-21-12)

b. A registrant engaging in more than one (1) group of independent activities, as defined by federal law, must obtain a separate Idaho controlled substance registration for each group of activities if not exempted from separate DEA registration by federal law. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

018. LICENSE AND REGISTRATION: REINSTATEMENT.
The Board may, at its discretion, consider reinstatement of a license or registration upon receipt of a written petition and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested. (3-21-12)

01. Satisfactory Evidence. If applicable, reinstatement applicants must also provide satisfactory evidence of completion of continuing education requirements and compliance with any direct orders of the Board. (3-21-12)

02. Additional Requirements. A pharmacist reinstatement applicant must provide evidence of completion of a minimum of thirty (30) CPE~~U~~s hours within the twenty-four (24) months prior to reinstatement application and may be required to appear before the Board. The Board may also, at its discretion, impose additional requirements on a pharmacist reinstatement applicant who has not practiced as a pharmacist for the preceding twelve (12) months or longer that may include taking and passing an examination, completion of forty (40) intern hours for each year away from the practice of pharmacy, completion of additional CPE~~U~~s hours, or other requirements determined necessary to acquire or demonstrate professional competency. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

021. FEE SCHEDULE.

01. Licenses -- Professionals. (3-21-12)

a. Original pharmacist license: one hundred dollars ($100). (3-21-12)

b. Licensure by reciprocity: two hundred fifty dollars ($250). (3-21-12)

c. Pharmacist license annual renewal. (3-21-12)

i. Active: ninety dollars ($90). (3-21-12)

ii. Inactive: fifty dollars ($50). (3-21-12)

d. Late payment processing: fifty dollars ($50). (3-21-12)

e. License reinstatement fee: seventy-five dollars ($75). (3-21-12)

02. Certificates of Registration -- Professionals. (3-21-12)

a. Pharmacist engaged in telepharmacy across state lines -- registration or annual renewal: two hundred fifty dollars ($250). (3-21-12)

b. Pharmacist intern - registration or annual renewal: fifty dollars ($50). (3-21-12)

c. Pharmacist extern registration and annual renewal: fifty dollars ($50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. (3-21-12)

d. Technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

e. Veterinary drug technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

f. Registration reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

03. Certificates of Registration and Licensure - Facilities. (3-21-12)

a. Retail pharmacy - registration or annual renewal: one hundred dollars ($100). (3-21-12)

b. Institutional facility - registration or annual renewal. (3-21-12)

i. Hospital pharmacy: one hundred dollars ($100). (3-21-12)

ii. Nursing home: thirty-five dollars ($35). (3-21-12)

iii. ~~*Hospital without a pharmacy*~~ Clinic: thirty-five dollars ($35). ~~*(3-21-12)*~~( )

c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars ($100). (3-21-12)

d. Wholesaler. (3-21-12)

i. License or annual renewal: one hundred thirty dollars ($130); or (3-21-12)

ii. Registration or annual renewal: one hundred dollars ($100). (3-21-12)

e. Veterinary drug outlet - registration or annual renewal: one hundred dollars ($100). (3-21-12)

f. Telepharmacy across state lines - registration or annual renewal: one hundred dollars ($100). (3-21-12)

g. Mail service pharmacy. (3-21-12)

i. Initial license: five hundred dollars ($500). (3-21-12)

ii. License annual renewal: two hundred fifty dollars ($250). (3-21-12)

h. Limited service outlet - registration or annual renewal. (3-21-12)

i. Limited service outlet, if not listed: one hundred dollars ($100). (3-21-12)

ii. ~~*Parenteral admixture*~~ Sterile product pharmacy: one hundred dollars ($100). ~~*(3-21-12)*~~( )

iii. Remote dispensing pharmacy: one hundred dollars ($100). (3-21-12)

iv. Facility operating a narcotic treatment program: one hundred dollars ($100). (3-21-12)

v. Durable medical equipment outlet: fifty dollars ($50). (3-21-12)

vi. Prescriber drug outlet: thirty five dollars ($35). (3-21-12)

i. Analytical or research lab -- registration or annual renewal: forty dollars ($40). (3-21-12)

j. Retail non-pharmacy outlets - registration or annual renewal. (3-21-12)

i. "A" (Stocks more than fifty (50) drug items): sixty dollars ($60). (3-21-12)

ii. "B" (Stocks fifty (50) or fewer drug items): twenty-five dollars ($25). (3-21-12)

iii. "V" (Vending machines): ten dollars ($10) per machine. (3-21-12)

k. Supplemental facility registrations or annual renewals. (3-21-12)

i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration

required for one (1) or more hoods: no charge. (3-21-12)

ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)

l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

04. Controlled Substance Registration. (3-21-12)

a. Controlled substance - registration or annual renewal: sixty dollars ($60). (3-21-12)

b. Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars ($100). (3-21-12)

c. Controlled substance registration reinstatement: seventy-five dollars ($75). (3-21-12)

05. Administrative Services and Publications. (3-21-12)

a. Experiential hours certification: twenty-five dollars ($25). (3-21-12)

b. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). (3-21-12)

c. Duplicate registration or license card: ten dollars ($10). (3-21-12)

d. Commercial lists. (3-21-12)

i. Pharmacy list: fifty dollars ($50). (3-21-12)

ii. Pharmacist list: fifty dollars ($50). (3-21-12)

iii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). (3-21-12)

e. Official Idaho Register: fifteen dollars ($15). (3-21-12)

f. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). (3-21-12)

g. Hearing transcript: five dollars ($5) per page. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

034. PHARMACIST INACTIVE STATUS LICENSE.

01. Required Criteria. Upon Board approval, an inactive status pharmacist license may be issued if an applicant: (3-21-12)

a. Is a pharmacist in the state of Idaho licensed in good standing; (3-21-12)

b. Is unable or unwilling to practice pharmacy due to physical limitations or changes in circumstance; and (3-21-12)

c. Has submitted the required application. (3-21-12)

02. Exemptions and Restrictions. Inactive status licensees are exempt from CPE requirements and are prohibited from engaging in the practice of pharmacy while on inactive status. (3-21-12)

03. Return to Active Status. If an inactive status licensee wishes to return to active status, the licensee must ~~complete a minimum of thirty (30) CPEUs and~~ comply with the reinstatement requirements of these rules. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

052. CPE: REQUIREMENTS.
Each pharmacist applicant for license renewal must annually complete ~~the equivalent of one and one-half (1.5)~~ fifteen (15) CPE ~~units (CPEU)~~ hours. ~~One (1) CPEU is the equivalent of ten (10) clock hours of participation in programs approved by the Board.~~ ~~(3-21-12)~~( )

01. ACPE or CME. At a minimum, eight (8) ~~clock~~ of the CPE hours ~~(0.8 CPEU)~~ obtained must be all or a combination of ACPE or CME accredited programs. ACPE accredited activities must have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ~~(3-21-12)~~( )

02. Pharmacy Law. One (1) ~~clock~~ of the CPE hours ~~(0.1 CPEU)~~ obtained must be ACPE accredited or Board approved jurisprudence (pharmacy law) programs. ~~(3-21-12)~~( )

03. Board Approved. A maximum of six (6) ~~clock~~ of the CPE hours ~~(0.6 CPEU)~~ obtained may be Board-approved programs not accredited through ACPE or CME. ~~(3-21-12)~~( )

04. Live Attendance. Three (3) ~~clock~~ of the CPE hours ~~(0.3 CPEU)~~ obtained must be ~~obtained~~ by attendance at live or synchronous online CPE programs. ~~(3-21-12)~~( )

05. Carryover of Certain Unused Units. ~~Clock~~ CPE hours ~~of CPEU~~ accrued during June of a licensing period may be carried over into the next licensing period to the extent that a pharmacist's total ~~clock~~ CPE hours ~~of CPEU~~ for the current licensing period exceed the total CPE~~U~~s hours required by these rules.~~(3-21-12)~~( )

06. New Pharmacist Exemption. Recent pharmacist graduates applying for the first license renewal are not required to complete or certify the annual CPE requirements. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

110. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its authenticity and validity. (3-21-12)

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued: (3-21-12)

a. In good faith; (3-21-12)

b. For a legitimate medical purpose; (3-21-12)

c. By a licensed prescriber; (3-21-12)

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; (3-21-12)

e. Pursuant to a prescriber-patient relationship, unless statutorily exempted; and ~~(3-21-12)~~( )

f. In the form and including the elements required by law. (3-21-12)

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated.(3-21-12)

03. Tampering. A prescription drug order is invalid if it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. (3-21-12)

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (3-21-12)

05. Family Members. A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

115. PRESCRIPTION DRUG ORDER: TRANSFERS.

01. Communicating Prescription Drug Order Transfers. Except prescription drug orders for Schedule II controlled substances, a pharmacist may transfer prescription drug order information for the purpose of filling or refilling if the information is communicated from pharmacist to pharmacist verbally, electronically, or via fax. (3-21-12)

a. Prescription drug order information may also be communicated verbally by a student pharmacist, under the supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. (3-21-12)

b. If transferring by fax transmission, the transfer document used must be signed by the transferring pharmacist. (3-21-12)

02. Documentation Required of the Transferring Pharmacy. The pharmacist transferring prescription drug order information must void or otherwise indicate that the original prescription drug order has been transferred and record the following information: (3-21-12)

a. The name of the transferring pharmacist; (3-21-12)

b. The name of the receiving pharmacist; (3-21-12)

c. The name of the receiving pharmacy; (3-21-12)

d. The date of the transfer; (3-21-12)

e. The number of authorized refills available; and (3-21-12)

f. If written for a controlled substance, the address and DEA registration number of the receiving pharmacy. (3-21-12)

03. Documentation Required of the Receiving Pharmacy. The pharmacist receiving a transferred prescription drug order must document that the prescription drug order is a "transfer" and record the following information: (3-21-12)

a. The name of the receiving pharmacist; (3-21-12)

b. The name of the transferring pharmacist; (3-21-12)

c. The name of the transferring pharmacy; (3-21-12)

d. The date of issuance of the original prescription drug order; (3-21-12)

e. The number of refills authorized by the original prescription drug order; (3-21-12)

f. The number of authorized refills available; and (3-21-12)

g. If written for a controlled substance: (3-21-12)

i. The dates and locations of the original dispensing and previous refills; and (3-21-12)

ii. The name, address, DEA registration number, and the serial number assigned to the prescription ~~number of~~ by the transferring pharmacy for each dispensing and of the pharmacy that originally filled the prescription, if different. ~~(3-21-12)~~( )

04. Electronic Prescription Drug Order Transfers. For electronic prescription drug orders that are transferred electronically, the transferring pharmacist must provide all of the information required to be recorded by the receiving pharmacist in addition to the original electronic prescription data. The receiving pharmacist must create an electronic record for the prescription drug order that includes the receiving pharmacist's name and all of the information transferred with the prescription. (3-21-12)

05. Pharmacies Using Common Electronic Files. Pharmacies may establish and use a common electronic file to maintain required dispensing information. (3-21-12)

a. Pharmacies using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other pharmacies sharing the common electronic file. (3-21-12)

b. Common electronic files must contain complete and accurate records of each prescription and refill dispensed. (3-21-12)

06. Transferring Prescription Drug Orders for Controlled Substances. A prescription drug order for a controlled substance listed in Schedules III, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. (3-21-12)

07. Transferring Prescription Drug Order Refills. Prescription drug orders for non-controlled substances may be transferred more than one (1) time if there are refills remaining and other legal requirements are satisfied. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

204. CONTROLLED SUBSTANCES: PMP.
Specified data on controlled substances must be reported weekly, or more often as required by the Board, by all pharmacies holding a DEA retail pharmacy registration that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. ~~(3-21-12)~~( )

01. Online Access to PMP. Online access to the Board's PMP is limited to licensed prescribers and pharmacists for treatment purposes. To obtain online access, a prescriber or pharmacist must: (3-21-12)

a. Complete and submit a registration application and a written agreement to adhere to the access restrictions and limitations established by law; (3-21-12)

b. Obtain Board approval for access; and (3-21-12)

c. Be issued a user account, login name, and password. (3-21-12)

02. Use Outside Scope of Practice Prohibited. Information obtained from the PMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. (3-21-12)

03. Profile Requests. Authorized persons without online access may obtain a profile by completing the required form and submitting it to the Board office with proof of identification and other credentials required to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. (3-21-12)

04. Suspension, Revocation, or Restriction of PMP Access. Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's or pharmacist's authorization for online access to the PMP. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

330. PHARMACIST: ADMINISTERED IMMUNIZATIONS.

01. Patient Eligibility. A pharmacist may administer an immunization to a healthy patient without immunization contraindications pursuant to the latest recommendations by the CDC or other qualified government authority or to any patient pursuant to a prescription drug order issued by another prescriber. (3-21-12)

02. Pharmacist Qualifications. To qualify to administer immunizations, a pharmacist must first: (3-21-12)

a. Successfully complete an ACPE-accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the CDC's Advisory Committee on Immunization Practices and includes at least the following: (3-21-12)

i. Basic immunology, vaccine, and immunization protection; (3-21-12)

ii. Diseases that may be prevented by vaccination or immunization; (3-21-12)

iii. Current recommended immunization schedules; (3-21-12)

iv. Vaccine and immunization storage and management; (3-21-12)

v. Informed consent; (3-21-12)

vi. Physiology and techniques for administration of immunizations; (3-21-12)

vii. Pre-immunization and post-immunization assessment and counseling; (3-21-12)

viii. Immunization reporting and records management; and (3-21-12)

ix. Identification response, documentation, and reporting of adverse events. (3-21-12)

b. Hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program that includes cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training and requires a hands-on skills assessment by an authorized instructor. (3-21-12)

03. Maintaining Qualification. To maintain qualification to administer immunizations, a pharmacist must annually complete a minimum of one (1) ~~clock~~ CPE hour ~~(0.1 CPEU)~~ of ACPE-approved CPE related to vaccines, immunizations, or their administration, which may also be applied to the general CPE requirements of these rules. ~~(3-21-12)~~( )

04. Student Pharmacist Administration. A pharmacist may not delegate authority to administer immunizations; however, a student pharmacist who has satisfied the qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. (3-21-12)

05. Waste Disposal. An immunizing pharmacist must properly dispose of used or contaminated supplies. (3-21-12)

06. Required Reports. An immunizing pharmacist must report: (3-21-12)

a. Adverse events to the healthcare provider identified by the patient, if any, and to the Vaccine Adverse Event Reporting System (VAERS); and (3-21-12)

b. Administration of immunizations to the Idaho Immunization Reminder Information System (IRIS), as required. (3-21-12)

07. Required Resources. A pharmacist must have a current copy of, or on-site access to, the CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases. (3-21-12)

08. Vaccine Information Statements. A corresponding, current CDC-issued VIS must be provided to the patient or the patient's representative for each administered immunization. (3-21-12)

09. Recordkeeping. For each administered immunization, the following information must be collected and maintained in the patient profile: (3-21-12)

a. The patient's name, address, date of birth, and known allergies; (3-21-12)

b. The date of administration; (3-21-12)

c. The product name, manufacturer, dose, lot number, and expiration date of the vaccine; (3-21-12)

d. Documentation identifying the VIS provided; (3-21-12)

e. The site and route of administration and, if applicable, the dose in a series (e.g. one (1) of three (3)); (3-21-12)

f. The name of the patient's healthcare provider, if any; (3-21-12)

g. The name of the immunizing pharmacist and of the student pharmacist, if any; (3-21-12)

h. Adverse events observed or reported, if any, and documentation including at least the dates of any subsequent required reporting; and (3-21-12)

i. Completed informed consent forms. (3-21-12)

10. Emergencies. (3-21-12)

a. An immunizing pharmacist must maintain an immediately retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. (3-21-12)

b. An immunizing pharmacist may initiate and administer auto-inject epinephrine, intramuscular diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association. (3-21-12)

331. -- 3~~4~~5~~9~~9. (RESERVED)

3~~5~~6~~0~~0. STUDENT PHARMACIST: UTILIZATION AND PRACTICE LIMITATIONS.

01. Activities. A student pharmacist may engage in the practice activities of a pharmacist if: (3-21-12)

a. The activity is not specifically required to be performed only by a pharmacist; (3-21-12)

b. The activity is commensurate with the education and skill of the student pharmacist and performed under the supervision of a pharmacist; (3-21-12)

c. Any activity of a compounding, dispensing, or interpretive nature is checked by a pharmacist; and (3-21-12)

d. Any recording activity that requires the initial or signature of a pharmacist is countersigned by a pharmacist. (3-21-12)

02. Unlawful Acceptance of Assignment. A student pharmacist must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the student pharmacist is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

03. Identification of Student Pharmacists. (3-21-12)

a. Each student pharmacist must be identified by a clearly visible name badge designating the individual as a student pharmacist. The name badge must contain the individual's printed first name and the title of student pharmacist, pharmacist intern, pharmacist extern, or another title that conveys the same meaning. (3-21-12)

b. Student pharmacists must identify themselves as a student pharmacist, pharmacist intern, or pharmacist extern on any phone calls initiated or received while on duty. (3-21-12)

3~~5~~6~~1~~1. -- 399. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

601. PHARMACY SPACE AND FIXTURES.

01. Preparation Area Standards. A pharmacy must be well-lit, ventilated, temperature controlled, and have sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and sanitary condition appropriate for the safe preparation and compounding of prescriptions. (3-21-12)

02. Equipment and Fixture Standards. A pharmacy must be equipped with a sink with hot and cold water, appropriate fixtures for waste disposal, and refrigerated storage equipment of reasonable capacity. (3-21-12)

03. Additional Retail Pharmacy Requirements. A retail pharmacy that is new or remodeled after the effective date of this rule must: (3-21-12)

a. Provide and maintain a patient consultation area that affords the patient auditory and visual privacy, is accessible through an entrance and exit that does not require the patient to enter or traverse any part of the ~~*prescription preparation or drug storage*~~ secured area~~s~~ of the pharmacy, and is compliant with the Americans with Disabilities Act; and ~~*(3-21-12)*~~( )

b. Include a lavatory facility in the pharmacy restricted to pharmacy staff. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

631. INSTITUTIONAL FACILITY: EMERGENCY DRUG ACCESS AND PHARMACIST ABSENCE. The director must make advance arrangements necessary to facilitate continuity of patient care and for the provision of drugs to the medical staff and other authorized personnel of the institutional facility in emergencies and during the absences of a pharmacist in compliance with this rule. (3-21-12)

01. Emergency Pharmacy Access. If a drug is unavailable from any other authorized emergency source in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug and in the absence of a pharmacist from the premises of the institutional facility, it may be retrieved from an institutional pharmacy by an R.N. as follows: (3-21-12)

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; (3-21-12)

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access; and (3-21-12)

c. Only a non-controlled substance may be removed and only in an amount necessary to treat a patient's immediate need until the pharmacy is again attended by a pharmacist. (3-21-12)

02. Emergency Cabinets. A cabinet or similar enclosure located outside an institutional pharmacy may be used for emergency access of drugs by an R.N. as follows: (3-21-12)

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; and (3-21-12)

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. (3-21-12)

03. Emergency Drug Access Conditions and Documentation. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows: (3-21-12)

a. Removal of a drug must be pursuant to a valid drug order; (3-21-12)

b. Removal of a drug must be documented in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The ~~*signature*~~ initials or other unique identifier of the designated nurse. ~~*(3-21-12)*~~( )

c. The removal record and a copy of the drug order must be left conspicuously in the pharmacy, emergency cabinet, or alternative location to facilitate prompt accuracy verification and initialing by a pharmacist. (3-21-12)

04. Temporary Pharmacist Absence. To accommodate periods of temporary absence of a pharmacist from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions: (3-21-12)

a. No other person may be allowed access or entrance to the pharmacy; (3-21-12)

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and (3-21-12)

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

640. INSTITUTIONAL FACILITY: OFFSITE PHARMACY PRACTICE STANDARDS.

01. Offsite Pharmacy Services. If an institutional facility without an institutional pharmacy obtains drugs, devices, or other pharmacy services from outside the institutional facility, arrangements must be made to ensure that the offsite pharmacy provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and properly serve the needs of the facility. (3-21-12)

02. Written Agreement. The arrangements must be made in writing and must, at a minimum, specify that: (3-21-12)

a. An offsite pharmacist will act in the capacity of a part-time director; (3-21-12)

b. For nursing homes, on-call services by a pharmacist will be available at all times; (3-21-12)

c. The pharmacy will provide adequate storage facilities for drugs; and (3-21-12)

d. Drugs housed in an LTCF must be labeled as required by the ~~*general provisions of these*~~ standard prescription drug labeling rule~~s~~ and, unless maintained in an electronic record, must include a lot number for administration of recalls. ~~*(3-21-12)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

750. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: (3-21-12)

a. Operational procedures for the appropriate provision and delivery of equipment; (3-21-12)

b. Operational procedures for maintenance and repair of equipment; and (3-21-12)

c. Recordkeeping requirements for documenting the acquisition and provision of products. (3-21-12)

02. ~~*DME Outlet*~~ Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: ~~*(3-21-12)*~~( )

a. Pure oxygen for human application; (3-21-12)

b. Nitrous oxide; (3-21-12)

c. Sterile sodium chloride; and (3-21-12)

d. Sterile water for injection. (3-21-12)

03. Prescriber's Order Required. Prescription drugs and devices may only be sold or delivered by a DME outlet upon the lawful order of a prescriber. DME outlets may hold drugs that are not prescription drugs for sale. (3-21-12)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1202

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 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 17, 2012.

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:

Post 2012 complete rule re-write, this rulemaking docket clarifies confusing, absent, and incomplete language. The rulemaking will add, strike and clarify definitions; add an acronym; harmonize terms; reduce license and registration posting requirement; clarify that technicians-in-training must obtain and maintain employment; clarify that student pharmacists and technician registrations may be cancelled if the registrants no longer meet the minimum requirements; clarify student pharmacist registration; clarify that a prescriber can designate “brand only” verbally; clarify who initials certain labels; clarify who is exempt from obtaining positive identification; reintroduce previously struck seven (7)-day allowance for annual inventory; clarify that all drugs must be stored according to rule; clarify that prescriptions can be delivered to a correctional facility; clarify that a pharmacy can not open without a pharmacist-in-charge or a director; clarify the conditions when a pharmacist may be absent from a retail pharmacy while the pharmacy remains open; add a grandfathering provision to a security requirement; clarify the required public notification by a pharmacy of its change in hours open for business; clarify pharmacy permanent closing procedures; clarify that a director must notify the Board of a change in employment; clarify the conditions under which dispensing can occur by a hospital’s emergency room; and clarify out-of-state mail service pharmacy’s toll free access by patients.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

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 Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 2, 2012 Idaho Administrative Bulletin, Vol. 12-5, Page 82, and in the August 1, 2012 Idaho Administrative Bulletin, Vol. 12-8, page 73, Docket No. 27-0101-1201.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 24, 2012.

DATED this 5th day of September, 2012.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Telephone: (208) 334-2356
FAX: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1202

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

01. Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)

02. ACPE. Accreditation Council for Pharmacy Education. (3-21-12)

03. Acute Care Hospital. A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)

04. ADS -- Automated Dispensing and Storage. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

05. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

06. Central Pharmacy. A pharmacy within the state or a registered telepharmacy across state lines with which centralized pharmacy services have been contracted. (3-21-12)

07. Centralized Pharmacy Services. The processing by a pharmacy of a request from another pharmacy to fill, refill, or dispense a prescription drug order or to perform processing functions such as prospective drug review. (3-21-12)

08. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)

09. Charitable Clinic or Center -- Authorized Personnel. A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)

10. Chart Order. A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

11. CME. Continuing medical education. (3-21-12)

12. COE -- Central Order Entry. A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically

located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)

13. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

14. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

15. Continuous Quality Improvement Program. 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. (3-21-12)

16. Correctional Facility. Any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order. ( )

16~~7~~7. CPE. Continuing pharmacy education. (3-21-12)

~~***17. CPEU**. Continuing pharmacy education unit.* (3-21-12)~~

18. DEA. United States Drug Enforcement Administration. (3-21-12)

19. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

20. DME. Durable medical equipment. (3-21-12)

21. Drug Order. A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)

22. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

23. Drug Product Substitution. Dispensing a drug product other than prescribed ~~*without the express permission of the prescriber and patient*~~. ~~(3-21-12)~~( )

24. DTM -- Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

25. Emergency Drugs. Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)

26. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

27. FDA. United States Food and Drug Administration. (3-21-12)

28. Flavoring Agent. An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)

29. Floor Stock. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

30. **FPGEC**. Foreign Pharmacy Graduate Examination Committee. ( )

301. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

312. **Hospital System**. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

323. **Idaho State Board of Pharmacy or Idaho Board of Pharmacy**. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (3-21-12)

334. **Individually Identifiable Health Information**. Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)

b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)

i. Identifies the individual; or (3-21-12)

ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)

345. **Institution Engaged in The Practice of Telepharmacy Across State Lines**. An institutional facility engaged in the practice of telepharmacy into Idaho that is an out-of-state hospital with an institutional pharmacy licensed or registered in another state or a COE pharmacy licensed or registered in another state that is part of a hospital system. (3-21-12)

356. **Institutional Pharmacy**. A pharmacy located in an institutional facility. (3-21-12)

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. **LTCF -- Long-Term Care Facility**. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. **MPJE**. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

03. **MTM -- Medication Therapy Management**. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

04. **NABP**. National Association of Boards of Pharmacy. (3-21-12)

05. **NAPLEX**. North American Pharmacists Licensure Examination. (3-21-12)

06. **NDC**. National Drug Code. (3-21-12)

07. **Non-Institutional Pharmacy**. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

08. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

09. **Pharmaceutical Care Services**. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Nothing in these rules allows a pharmacist, beyond what is statutorily allowed or allowed by a collaborative practice agreement, to diagnose, prescribe, order lab tests, or conduct complete physical exams. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (3-21-12)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; and (3-21-12)

m. Other services as allowed by law. (3-21-12)

10. **Pharmacist Extern**. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy ~~*and is obtaining practical experience under the supervision of a pharmacist*~~. ~~*(3-21-12)*~~( )

11. Pharmacist Intern. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

12. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

13. PHI -- Protected Health Information. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)

14. PIC. Pharmacist-in-charge. (3-21-12)

15. PMP. Prescription Monitoring Program. (3-21-12)

16. Prepackaging. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)

17. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

18. Prescriber Drug Outlet. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

19. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

20. Relative Contraindication. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

21. Remote Dispensing Site. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

22. Retail Non-Pharmacy Drug Outlet. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

23. Retail Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

24. **R.N**. Registered nurse. (3-21-12)

012. DEFINITIONS AND ABBREVIATIONS (S -- Z).

01. **Sample**. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (3-21-12)

02. **Secured Pharmacy**. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-21-12)

03. **Skilled Nursing Facility**. An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (3-21-12)

04. **Student Pharmacist**. A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. (3-21-12)

05. **Technician**. Unless specifically differentiated, a term inclusive of pharmacy technician, certified pharmacy technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (3-21-12)

06. **Telepharmacy**. The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (3-21-12)

07. **Therapeutic Equivalent Drugs**. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). ~~(3-21-12)~~( )

08. **Unit Dose**. Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (3-21-12)

09. **USP**. United States Pharmacopeia. (3-21-12)

10. **USP-NF**. United State Pharmacopeia-National Formulary. (3-21-12)

11. **VAWD -- Verified Accredited Wholesale Distributor**. An accreditation program for wholesale distributors offered through NABP. (3-21-12)

12. **VDO -- Veterinary Drug Outlet**. A registered establishment that employs a qualified VDT to distribute prescription veterinary drugs pursuant to lawful orders of a veterinarian. (3-21-12)

13. **VDT -- Veterinary Drug Technician**. A non-pharmacist qualified by registration with the Board to distribute prescription veterinary drugs in a VDO. (3-21-12)

14. **Veterinary Drug Order**. A lawful order by a veterinarian issued pursuant to the establishment of a veterinarian-patient-client relationship as recognized by the American Veterinary Medical Association. (3-21-12)

15. **VIS**. Vaccine Information Statement. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

019. LICENSE AND REGISTRATION: ~~POSTING~~ INSPECTION.
Licenses and registrations issued under the Idaho Pharmacy and the Uniform Controlled Substances Acts must be ~~conspicuously posted~~ immediately retrievable at the licensed or registered location or at the drug outlet where the licensee or registrant is employed. ~~(3-21-12)~~( )

01. Application Pending. Pending receipt of the current registration or license from the Board, the confirmation of successful submission of an online application must be printed ~~and posted~~. ~~(3-21-12)~~( )

02. Temporary Locations. A licensee or registrant engaged in professional practice at a temporary or alternate location or in training must be able to produce written proof of licensure or registration immediately upon request. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

01. Licensure Submission Requirements. To be considered for licensure, a graduate of a school or college of pharmacy located outside of the United States must submit an application for licensure by examination, certification by the ~~Foreign Pharmacy Graduate Examination Committee (~~FPGEC~~)~~, and certification of completion of a minimum of fifteen hundred (1500) experiential hours. ~~(3-21-12)~~( )

02. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

036. STUDENT PHARMACIST REGISTRATION.

01. Registration Requirements. ( )

a. To be approved for and maintain registration as a pharmacist extern, the applicant must currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy. ( )

b. To be approved for and maintain registration as a pharmacist intern, the applicant must be: ( )

i. A graduate of an accredited school or college of pharmacy within the United States or; ( )

ii. A graduate of a school or college of pharmacy located outside the United States and obtain certification by the FPGEC. ( )

02. Renewal. ( )

a. ~~Unless revoked or suspended by the Board, a~~A pharmacist extern registration must be renewed annually ~~on~~ by July 15; however, the renewal fee will be waived for the duration of the ~~extern's~~ student's enrollment in the school or college of pharmacy and until July 15 following graduation. ~~(3-21-12)~~( )

b. A pharmacist intern registration must be renewed annually by June 30. ( )

03. Cancellation of Registration. Failure to maintain the requirements for student pharmacist registration will result in the cancellation of registration. ( )

(BREAK IN CONTINUITY OF SECTIONS)

041. TECHNICIAN-IN-TRAINING REGISTRATION.
A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a technician and obtains and maintains employment as a technician-in-training. ~~(3-21-12)~~( )

01. Duties. Upon registration, a technician-in-training may perform any of the duties allowed by statute or rule to be delegated to a registered technician under the supervision of a pharmacist. (3-21-12)

02. Renewal. The registration of a technician-in-training ~~expires on~~ must be renewed by June 30, ~~and~~ but is only renewable two (2) times. ~~(3-21-12)~~( )

03. Registration Expiration. Upon the final expiration of a technician-in-training registration, a person must satisfy the technician certification and registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (3-21-12)

04. Cancellation of Registration. Failure to maintain employment will result in the cancellation of the registration. ( )

042. PHARMACY TECHNICIAN CERTIFICATION: CONTINUOUS EMPLOYMENT EXEMPTION.
A technician registered with the Board and employed as a technician on June 30, 2009, is not required to obtain or maintain certification as a condition of registration renewal after June 30, 2009, as long as the registrant remains continuously employed as a technician by the same employer. If a registrant that qualifies for this exemption disrupts continuous employment as a technician with one employer, the technician registration will ~~correspondingly terminate on the date of employment termination~~ become invalid. The person must thereafter satisfy the certified pharmacy technician registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

131. DRUG PRODUCT: SELECTION.
Drug product selection is allowed only between therapeutic equivalent drugs. (3-21-12)

01. ~~Method of~~ Brand Name Drug ~~Product Selection~~ Dispensing. If ~~A~~a ~~branded product must be dispensed only if "BRAND ONLY" is specified by the~~ prescriber ~~on the electronic prescription~~ orders by any means that a brand name drug ~~order or on the face of a paper prescription~~ must be dispensed, then no drug ~~order by a "BRAND ONLY" check box or a handwritten notation~~ selection is permitted. ~~(3-21-12)~~( )

02. ~~Drug Product Selection~~ Documentation. If a generic is selected by a non-institutional pharmacy, the name of the drug and the manufacturer or the NDC number must be documented in the patient medication record. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

140. STANDARD PRESCRIPTION DRUG LABELING.
Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (3-21-12)

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business); (3-21-12)

02. ~~***Prescription***~~ **Serial Number**. The ~~*prescription*~~ serial number; ~~*(3-21-12)*~~( )

03. **Date**. The date the prescription is filled; (3-21-12)

04. **Prescriber**. The name of the prescriber; (3-21-12)

05. **Patient**. The name of the patient, and if the patient is an animal, the species; (3-21-12)

06. **Drug Name and Strength**. Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name); (3-21-12)

07. **Quantity**. The quantity of item dispensed; (3-21-12)

08. **Directions**. The directions for use; (3-21-12)

09. **Cautionary Information**. Cautionary information as required or deemed appropriate for proper use and patient safety; (3-21-12)

10. **Expiration**. An expiration date that is the lesser of: (3-21-12)

a. One (1) year from the date of dispensing; (3-21-12)

b. The manufacturer's original expiration date; (3-21-12)

c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)

d. A shorter period if warranted; (3-21-12)

11. **Refills**. The number of refills remaining, if any, or the last date through which the prescription is refillable; and (3-21-12)

12. **Warning**. The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." (3-21-12)

13. **Pharmacist Identification**. The initials or other unique identifier of the dispensing pharmacist. ( )

(BREAK IN CONTINUITY OF SECTIONS)

142. PARENTERAL ADMIXTURE LABELING.
If one or more drugs are added to a parenteral admixture the admixture's container must include a distinctive, supplementary label with at least the following information: (3-21-12)

01. **Ingredient Information**. The name, amount, strength, and if applicable, the concentration of the drug additive and the base solution or diluent; (3-21-12)

02. **Date and Time**. The date and time of the addition, or alternatively, the beyond use date and time; (3-21-12)

03. ~~***Preparer***~~ **Identification**. The initials or other unique identifier of the ~~*person who added the drug or drugs*~~ pharmacist or preparing prescriber responsible for its accuracy; ~~*(3-21-12)*~~( )

04. Prescribed Administration Regimen. The rate or appropriate route of administration or both, as applicable; and (3-21-12)

05. Special Instructions. Any special handling, storage, or device-specific instructions. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

200. CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.
A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. (3-21-12)

01. Positive Identification Presumed. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: (3-21-12)

a. The controlled substance will be paid for, in whole or in part, by an insurer; or (3-21-12)

b. The ~~*dispenser is part of the institutional facility where the*~~ patient is being treated at an institutional facility or is housed in a correctional facility. ~~*(3-21-12)*~~( )

c. The filled prescription is delivered to the patient's residence either by mail, common carrier, or an employee of the pharmacy. ( )

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a pharmacy or prescriber drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: (3-21-12)

a. The recipient's name (if other than the patient); (3-21-12)

b. A notation indicating that the recipient was known to the staff member; and (3-21-12)

c. The identity of the staff member making the personal identification. (3-21-12)

03. Acceptable Identification. The identification presented must include an unaltered photograph and signature and acceptable forms include a valid state or military driver's license or identification card and a valid passport. (3-21-12)

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and must include: (3-21-12)

a. A copy of the identification presented; or (3-21-12)

b. A record that includes: (3-21-12)

i. The recipient's name; (3-21-12)

ii. A notation of the type of identification presented; (3-21-12)

iii. The state, military branch, or other government entity that issued the identification; and (3-21-12)

iv. The identification number of the driver's license, identification card, or passport. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

206. CONTROLLED SUBSTANCES: INVENTORIES.

01. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand ~~*at least every twelve (12) months*~~ annually within seven (7) days of the date of the prior year's inventory in a form and manner that satisfies the inventory requirements of federal law. ~~*(3-21-12)*~~( )

02. Separate Inventories for Each Location. A separate controlled substances inventory must be taken and retained at each registered location. (3-21-12)

03. Inventory on PIC or Director Change. A complete controlled substance inventory must be conducted in the event of a change of PIC ~~*change*~~ or director on or by the first day of employment of the incoming PIC or director. ~~*(3-21-12)*~~( )

04. Inventory After Discovery of Theft or Loss. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. (3-21-12)

05. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory. (3-21-12)

06. Annual Inventory Compliance. Complete inventories conducted as otherwise required by these rules may also be considered in complying with the annual inventory requirement. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

260. DRUG PRODUCT STORAGE.

~~*Prescription d*~~Drugs~~*, controlled substances, or other items restricted to sale, dispensing, or administration by, or under the supervision of, a pharmacist or other registrant*~~ must be stored in accordance with USP-NF requirements in an area maintained and secured appropriately to safeguard product integrity and protect against product theft or diversion. ~~*(3-21-12)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

503. PRESCRIPTION DELIVERY RESTRICTIONS.

A pharmacist must not participate in any arrangement or agreement whereby filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not registered as a pharmacy except that a pharmacist or a pharmacy, by means of its agent, may deliver filled prescriptions to the patient, the patient's residence, the hospital or other institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed, or if a non-controlled substance, to the patient's licensed or registered healthcare provider. ~~*(3-21-12)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

600. PHARMACY REGISTRANT AND PIC OR DIRECTOR.

01. Designated PIC or Director Required. A new pharmacy must have a designated PIC or director by the date of opening and must not ~~*be without*~~ thereafter allow a vacancy or lapse in appointment of a designated PIC or director to continue for more than thirty (30) sequential days. ~~*(3-21-12)*~~( )

02. Corresponding and Individual Responsibility. The pharmacy registrant and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

605. PHARMACY SECURITY.

01. Basic Security Standards. A pharmacy must be constructed and equipped with adequate security, and at least while closed, utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. Pharmacies without an alarm or other monitoring system as of the effective date of this rule must comply with this rule upon completion of a structural remodel. (3-21-12)

02. Non-Institutional Pharmacy Security During Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except: ( )

a. ~~*for*~~ If a technician or student pharmacist is on to duty, to allow brief pharmacist absences within the business establishment; or ( )

b. ~~*t*~~To perform professional services in the peripheral areas immediately outside of the pharmacy. ~~*(3-21-12)*~~( )

03. Structural Security Requirements. If a pharmacy is located within an establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. (3-21-12)

a. Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (3-21-12)

b. Solid core or metal doors are required for new or remodeled pharmacies after the effective date of this rule. ~~*(3-21-12)*~~( )

c. Doors and other access points must be constructed in a manner that the hinge hardware is accessible only from inside of the pharmacy and must be equipped with locking devices. (3-21-12)

d. If used, a "drop box" or "mail slot" allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment. (3-21-12)

04. Restricted Access to the Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist or except as permitted by these rules for an institutional pharmacy. (3-21-12)

606. PHARMACY NOTIFICATION AND ADVERTISING OF HOURS OPEN FOR BUSINESS.

01. Notification of Business Hours. A pharmacy must notify the Board and prominently display the hours open to the public for business, if applicable, on or adjacent to its entrance and the entrance of the business establishment in which it is located if the open hours are different. (3-21-12)

02. Notification of Change of Business Hours. The Board and the public must be notified of changes to the hours that a pharmacy is open to the public for business, including changes resulting in differential hours, at least seven (7) days prior to the change except changes of hours in recognition of state holidays set forth in Section 73-108, Idaho Code. A change of hours for a holiday must be prominently posted for public notice at least seven (7) days in advance. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

609. PHARMACY CHANGE OF OWNERSHIP OR PERMANENT CLOSING.

01. Board Notification. The registrant must notify the Board of a pharmacy's change of ownership or permanent closure at least ten (10) days prior to the event. The notice must include: (3-21-12)

a. The name and address of the pharmacy to be sold or closed; (3-21-12)

b. The date of sale or closure; (3-21-12)

c. The name and address of the business acquiring the prescription inventory; and (3-21-12)

d. The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. (3-21-12)

02. Public Notice. A registrant must notify the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the date of closure and the new location of the prescription files. Notice must be provided by prominent posting in a public area of the pharmacy. (3-21-12)

03. Pharmacy Signs. Unless sold and transferred to another pharmacy operator, a registrant must remove or completely cover each sign and other exterior indication that the premises was a pharmacy within thirty (30) days after the date a pharmacy permanently ceases operations. (3-21-12)

04. Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must: ( )

a. Adequately secure and protect the prescription files from unlawful use or disclosure; ( )

b. Secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition; and ~~must~~ ( )

c. ~~r~~Retain a closing inventory of controlled substances. ~~(3-21-12)~~( )

05. Pharmacy Change of Ownership. A change of ownership of a currently registered pharmacy will require the submission and approval of a new pharmacy registration application but will not require an onsite inspection prior to issuance of a pharmacy registration unless structural remodeling occurs. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

622. INSTITUTIONAL PHARMACY: DIRECTOR: MINIMUM RESPONSIBILITIES.

Each institutional pharmacy must be supervised and directed by an Idaho-licensed pharmacist (referred to herein as "the director") who is knowledgeable in, and thoroughly familiar with, the specialized functions of institutional pharmacies. The director is responsible for ensuring compliance with applicable law and for each activity of the institutional pharmacy, including at least the following: (3-21-12)

01. Policies and Procedures. In coordination with the appropriate institutional facility personnel, the adoption of policies and procedures with sufficient specificity regarding the handling, storage, and dispensing of drugs within the institution to protect public health and safety and ensure compliance with these rules and other applicable law. (3-21-12)

02. Formulary or Drug List Development. The participation in any development of a formulary or drug list for the facility. (3-21-12)

03. Product Procurement. The procurement of drugs, chemicals, biologicals, devices, or other products used by the institutional facility for patient pharmaceutical care services or for which a drug order is required. (3-21-12)

04. Drug Use, Storage, and Accountability. The safe and efficient dispensing, distribution, control, and secured storage of, and accountability for, drugs within the facility, including at least the following: (3-21-12)

a. Ensuring that drugs stored within the institutional pharmacy or in alternative secured storage areas have proper sanitation, temperature, light, ventilation, moisture control, segregation and security; (3-21-12)

b. Ensuring that outdated or other unusable drugs are identified and stored in a manner that prevents their distribution or administration prior to disposition; (3-21-12)

c. Ensuring that emergency drugs are in adequate and proper supply at designated locations; (3-21-12)

d. Ensuring that requirements applicable to the purchasing, storing, distribution, dispensing, recordkeeping, and disposal of controlled substances are met throughout the institution, including but not limited to, ensuring that controlled substances stored in surgery or emergency departments, nursing stations, ambulatory clinics, diagnostic laboratories or other locations outside of the pharmacy are inaccessible to unauthorized personnel; (3-21-12)

e. Ensuring accurate filling and labeling of containers from which drugs are to be administered or dispensed; (3-21-12)

f. Ensuring appropriate admixture of parenteral products, including serving in an advisory capacity for nursing personnel concerning incompatibility and the provision of proper incompatibility information; and (3-21-12)

g. Ensuring appropriate provision and maintenance, in both the pharmacy and patient care areas, of a sufficient inventory of antidotes and other emergency drugs, current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and other materials and information determined necessary by the appropriate institutional facility personnel. (3-21-12)

05. Emergency Drug Access Protocol. In coordination with the appropriate institutional facility personnel, the development of an emergency drug access protocol and related training of R.N.s to ensure appropriate knowledge of the proper methods of access, removal of drugs, documentation, and other required procedures prior to the R.N.'s designation for access to emergency drug supplies. (3-21-12)

06. Suspected Adverse Drug Reaction Reporting. The reporting in a timely manner of a suspected adverse drug reaction to the ordering physician and to the appropriate institutional facility personnel. The director may use discretion and, if deemed necessary or advisable for public health or safety, report a suspected reaction to others such as MedWatch, the manufacturer, and the USP. (3-21-12)

07. Records Maintenance. The maintenance of records of institutional pharmacy transactions required by law. (3-21-12)

08. Teaching, Research, and Patient Care Evaluation Programs. The cooperation with any teaching and research programs and the participation in any patient care evaluation programs relating to pharmaceutical utilization and effectiveness within the institutional facility. (3-21-12)

09. Continuous Quality Improvement Program. The development and implementation of a continuous quality improvement program to review and evaluate pharmaceutical services and recommend improvements. (3-21-12)

10. Director Change. Both an outgoing and incoming director must report to the Board a change in the institutional pharmacy director within ten (10) days of the change. ( )

(BREAK IN CONTINUITY OF SECTIONS)

637. INSTITUTIONAL FACILITY: EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.

~~*A limited supply of d*~~Drugs~~*, not including Schedule II controlled substances,*~~ may be ~~*approved for delivery*~~ delivered by an RN to outpatients ~~*receiving*~~ being treated in a hospital emergency room ~~*treatment if stored in the emergency room pursuant to applicable law and these rules pertaining to emergency drug product storage and if accessed and delivered as permitted or restricted by this rule.*~~ as follows: ~~*(3-21-12)*~~( )

01. Prerequisites: ( )

a. In the presence of a prescriber, acting as an agent of that prescriber, or outside the presence of a prescriber, when there is no prescriber present in the hospital in accordance with applicable state and federal law; ( )

b. Pursuant to a valid drug order issued by a prescriber; ( )

c. When no pharmacist is on duty in the community; and ( )

d. When drugs are stored and accessed in accordance with applicable laws and rules. ( )

0~~1~~2. Limitations. No more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (3-21-12)

0~~2~~3. Documentation. Delivery ~~*must occur only pursuant to a valid drug order and*~~ must be documented as required by these rules for institutional facility emergency drug access. ~~*(3-21-12)*~~( )

0~~3~~4. Labeling. The institutional pharmacy must prepackage and affix ~~*A*~~a label ~~*must be affixed*~~ to the container with the information required by ~~*these*~~ the standard prescription drug labeling rules, except that blank spaces may be left for ~~*outpatient dispensing*~~ the names of the patient and prescriber and directions for use. ~~*(3-21-12)*~~( )

~~***04. R.N. Staff Personnel Only.*** *This rule does not authorize any person other than an R.N. on a hospital's emergency room staff to prepare or deliver prescription drugs to outpatients receiving emergency treatment.* *(3-21-12)*~~

(BREAK IN CONTINUITY OF SECTIONS)

713. -- 729. (RESERVED)

730. OUT-OF-STATE MAIL SERVICE PHARMACY.
An out-of-state mail service pharmacy, during its regular hours of operation, but no less than forty (40) hours in six (6) days per week, provide a toll-free telephone service to facilitate communication between Idaho patients and a pharmacist with access to the patient records. This toll-free number must be disclosed on the prescription label for drugs dispensed to Idaho patients. ( )

731. -- 749. (RESERVED)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1203

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 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 17, 2012.

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:

As requested by a rural, Idaho hospital to improve patient safety. This rulemaking docket would expand the use of self-service automated dispensing and storage systems (ADS) to hospital emergency rooms (ER).

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

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 Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 2, 2012 Idaho Administrative Bulletin, Vol. 12-5, Page 82, and in the August 1, 2012 Idaho Administrative Bulletin, Vol. 12-8, page 73, Docket No. 27-0101-1201.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 24, 2012.

DATED this 7th day of Aeptember, 2012.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1203

IDAPA 27
TITLE 01
CHAPTER 01

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

290. ADS SYSTEMS: MINIMUM STANDARDS.
This rule establishes the minimum standards for the use of an ADS system to dispense and store drugs and devices. (3-21-12)

01. System Registration and Approved Utilization Locations. One or more ADS systems may be utilized by the following drug outlets if registered as required by the Board: (3-21-12)

a. In a pharmacy, remote dispensing site, or other ambulatory healthcare setting where utilization of the ADS system is under the adequate personal or electronic supervision of a pharmacist, as defined by these rules; (3-21-12)

b. In a prescriber drug outlet; and (3-21-12)

c. In an institutional facility. (3-21-12)

02. Multiple System Documentation. At least the following documentation must be maintained for each ADS system by the supervising pharmacy or prescriber drug outlet utilizing multiple ADS systems: (3-21-12)

a. The manufacturer's name and model of the ADS system; (3-21-12)

b. The state and, if applicable, federal ADS system registrations; and (3-21-12)

c. The name, address, and specific location where the ADS system is operational. (3-21-12)

03. System Access, Monitoring, and Control. Access to the ADS system must be monitored and controlled as follows: (3-21-12)

a. Proper identification controls, including electronic passwords or other coded identification, must be utilized and access control must be limited and authorized by the prescriber, PIC, or director; (3-21-12)

b. The prescriber, PIC, or director must be able to stop or change access at any time; (3-21-12)

c. The prescriber, PIC, or director must maintain a current and immediately retrievable list of persons who have access and the limits of that access; (3-21-12)

d. Review of user access reports must be conducted periodically to ensure that access by persons no longer employed has been appropriately disabled; and (3-21-12)

e. Access for maintenance or repair must be pre-approved by the prescriber, PIC, or director and must be performed under the continuous supervision of a person with appropriate access authorization. (3-21-12)

04. System Security and Patient Confidentiality. The ADS system must have adequate system security and safeguards to prevent and detect unauthorized access or use, maintain the integrity of patient records and prescription drug orders, and protect patient privacy. (3-21-12)

05. System Filling, Stocking, Replenishing. The filling, stocking, or replenishing of drugs into the ADS system must be accomplished by a pharmacist, technician, prescriber, or authorized prescriber drug outlet

personnel. Timely pharmacist or prescriber verification of the accuracy of the filling, stocking, or replenishing of the ADS system must occur through a manual process, bar coding, or other electronic technology used for item identification. (3-21-12)

06. Stocked Drug Documentation. The ADS system must be able to generate a record on demand of drugs filled into the system that includes at least: (3-21-12)

a. The date; (3-21-12)

b. The drug name; (3-21-12)

c. The dosage form; (3-21-12)

d. The strength; (3-21-12)

e. The quantity; (3-21-12)

f. The drug expiration; (3-21-12)

g. The identity of the ADS system; and (3-21-12)

h. The name or initials of the authorized individual filling the ADS system and, if applicable, the verifying pharmacist or prescriber. (3-21-12)

07. System Access and Transaction Documentation. The ADS system must automatically document transactions and other events involving access to system contents that is immediately retrievable in written or electronic form and includes at least the following: (3-21-12)

a. The identity of the system and, if applicable, the component accessed; (3-21-12)

b. The name or other identification (e.g., electronic signature or unique identifier) of the person conducting the transaction; (3-21-12)

c. The type of transaction; (3-21-12)

d. The date and time of transaction; (3-21-12)

e. The name, strength, dosage form, and quantity of the drug or description of the medical device accessed; and (3-21-12)

f. If applicable, the name of the patient for whom the drug was ordered. (3-21-12)

~~***08. Supervising Pharmacy Documentation**. The supervising pharmacy of a remote dispensing site must retain separate records of transactions and prescriptions processed by each ADS system utilized.* (3-21-12)~~

0~~9~~8. ADS System Used for Tablets or Capsules. The lot number of each drug contained in an ADS system used to store in bulk and to count tablets or capsules for dispensing must be retained in an immediately retrievable manner or posted on the device. (3-21-12)

~~1~~09. Prepackaged Bulk Drug Cartridges or Containers. If the ADS system uses removable cartridges or containers to hold bulk drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by an FDA-approved repackager that is licensed as a wholesaler. The prepackaged cartridges or containers may be sent to a remote dispensing site to be loaded into the ADS system by a pharmacist or a technician if: (3-21-12)

a. A pharmacist has verified the proper filling and labeling of the cartridge or container; (3-21-12)

b. The individual cartridges or containers are transported to the ADS system in a secure, tamper-evident container; and (3-21-12)

c. The ADS system utilizes technologies to ensure that the cartridges or containers are accurately loaded. (3-21-12)

1~~1~~0. ~~Self-Service ADS System~~ Temperature Sensitive Drugs. ~~An ADS system may be used for self-service delivery of prescriptions if in compliance with this rule.~~ ~~(3-21-12)~~

~~a.~~ Products that are temperature sensitive must not be provided unless the system is able to maintain required storage conditions. ~~(3-21-12)~~( )

~~b. Controlled substances and products that require additional preparation to be ready for patient use must not be provided.~~ ~~(3-21-12)~~

~~c. The system must be physically attached to the pharmacy or prescriber drug outlet in a manner that access to areas used to stock the device are only accessible through the pharmacy or prescriber drug outlet by authorized personnel.~~ ~~(3-21-12)~~

~~d. The system must be operational only during the operating hours of the pharmacy or prescriber drug outlet.~~ ~~(3-21-12)~~

~~e. A self service ADS system must not be used to deliver new prescriptions outside of a prescriber drug outlet.~~ ~~(3-21-12)~~

~~f. Prescribers utilizing a self service ADS system to deliver new prescriptions must provide patient counseling on all new medications.~~ ~~(3-21-12)~~

~~g. The use of a self service ADS system for prescription refills must comply with laws applicable to the provision of refills by a pharmacy and must provide a patient notification with information about how counseling may be obtained.~~ ~~(3-21-12)~~

~~12. Vending Machines. Only non-prescription medical supplies and drugs that are unrestricted for over-the-counter sale may be stored and sold in vending machines and are subject to inspection by the Board upon reasonable notice.~~ ~~(3-21-12)~~

291. ADS SYSTEMS: SELF-SERVICE SYSTEMS.
The use of self-service ADS systems must comply with the ADS system minimum standards and the requirements of this rule. ( )

01. System Requirements. ( )

a. The system must only be operational: ( )

i. During the operating hours of the pharmacy, or prescriber drug outlet respectively; or ( )

ii. In a hospital's emergency room if no pharmacist is on duty in the community. ( )

b. The system must be substantially constructed, utilize adequate security, and be: ( )

i. Physically attached or immediately adjacent to the interior of the pharmacy, prescriber drug outlet, or hospital emergency room in a manner that access to areas used to stock the device are only accessible through the pharmacy, prescriber drug outlet, or hospital emergency room by authorized personnel; or ( )

ii. Located within the hospital's emergency room or prescriber drug outlet. ( )

02. Dispensing Restrictions. ( )

a. Products requiring additional preparation for patient use must be dispensed by the system directly to a prescriber or registered nurse for subsequent preparation and not dispensed directly to the patient. ( )

b. A pharmacy system may only dispense drugs or devices that have been previously dispensed to the patient. ( )

c. Controlled substances are prohibited in a pharmacy or prescriber drug outlet system. ( )

d. Drugs must be prepackaged for use in hospital emergency room systems and no more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. ( )

e. Hospital emergency room systems must only dispense to hospital emergency room patients. ( )

f. Hospital emergency room systems vouchers or their equivalent must expire within twenty-four (24) hours. ( )

03. Counseling. ( )

a. When dispensed via a system in a prescriber drug outlet or a hospital's emergency room, a patient must receive counseling prior to receiving drugs or devices that have not been previously dispensed to the patient. ( )

b. Refilled or renewed drugs dispensed via a system must include written notification of how counseling may be obtained. ( )

04. Packaging and Labeling. Drugs dispensed via a system must be compliant with the standard prescription drug labeling rule, the prescription drug packaging rule, and other pertinent rules. ( )

29~~1~~2. ADS SYSTEMS: INSTITUTIONAL FACILITIES.
Institutional facilities utilizing one or more ADS systems must ensure compliance with the ADS system minimum standards~~, *as applicable,*~~ and the requirements of this rule. ~~*(3-21-12)*~~( )

01. Product Packaging and Labeling. Except as provided herein, drugs stored in the ADS system must be contained in the manufacturers' sealed, original packages or in prepackaged unit-of-use containers (e.g., unit dose tablet/capsule, tube of ointment, inhaler, etc.) and must be labeled as required by these rules. Exceptions to these packaging requirements include: (3-21-12)

a. Injectable drugs stored in a multi-dose vial (e.g., heparin) from which the drug may be withdrawn into a syringe or other delivery device for single patient use; or (3-21-12)

b. OTC products stored in a manufacturers' sealed, multi-dose container (e.g., antacids, analgesics) from which the drug may be withdrawn and placed into an appropriate container for single patient use. (3-21-12)

02. Pharmacist Review. A pharmacist must review the drug order prior to any removal from the system of a drug intended for immediate patient administration except if: (3-21-12)

a. The system is being used as an after-hours cabinet for drug dispensing in the absence of a pharmacist; (3-21-12)

b. The system is being used in place of an emergency kit; (3-21-12)

c. The system is being used to provide access to emergency drugs and only a quantity sufficient is removed to meet the immediate need of the patient; (3-21-12)

d. The drug is a subsequent dose from a previously reviewed drug order~~. Any change made to the drug order requires a new approval by a pharmacist prior to removing the drug.~~; or ~~(3-21-12)~~( )

e. The prescriber controls the drug administration process in procedural areas. ( )

03. ~~Product~~ Drug Returns. The ADS system must provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system ~~(e.g., a return bin).~~ ~~(3-21-12)~~

~~a.~~ A drug removed from a system but not administered to a patient ~~must~~ may be returned ~~to the pharmacy immediately or maintained in a manner that prevents access to~~ as follows if unopened, sealed, intact and stored in compliance with the ~~returned~~ drug ~~except~~ product storage rule ~~to return it to the pharmacy and except~~: ~~(3-21-12)~~( )

a. The pharmacy, immediately; ( )

b. The ADS system for immediate reuse by authorized personnel in hospitals utilizing bar code scanning technology at the bedside and the ADS system; ( )

c. The ADS return bin, until: ( )

i. Returned to the pharmacy; or ( )

ii. Returned to the ADS system; or ( )

d. An alternative, secure storage area until return to the pharmacy or the ADS is feasible only if the drug: ( )

i. ~~Items that are~~ Is too large or bulky to be inserted into the system's return bin; ~~(3-21-12)~~( )

ii. ~~Items r~~Requir~~ing~~es refrigeration; or ~~(3-21-12)~~( )

iii. Requires immediate accessibility for ~~l~~limited critical ~~care items for which inaccessibility would compromise~~ patient care. ~~(3-21-12)~~( )

~~b. A removed drug or device must not be returned directly to the system for immediate reissue or reuse.~~ ~~(3-21-12)~~

~~c. Once removed, a drug or device must not be reused or reissued except:~~ ~~(3-21-12)~~

~~i. Drugs stored after dispensing under the drug storage conditions required by these rules;~~ ~~(3-21-12)~~

~~ii. As supervised by the pharmacist; and~~ ~~(3-21-12)~~

~~iii. In unopened, sealed, intact, and unaltered containers.~~ ~~(3-21-12)~~

04. Wasted ~~and Discarded Drugs~~ Controlled Substances. If wasted before completing the transaction, ~~T~~the ~~ADS~~ system must provide a mechanism for ~~securing and~~ accounting for wasted ~~or discarded drugs~~ controlled substances. Waste documentation must include at least the following: ~~(3-21-12)~~( )

a. Date and time of transaction; (3-21-12)

b. Patient name and location; (3-21-12)

c. Drug and dose; (3-21-12)

~~d. Quantity of transaction;~~ ~~(3-21-12)~~

~~e~~d. Wasted amount; (3-21-12)

~~f. Beginning and ending count (for controlled substances only);~~ ~~(3-21-12)~~

~~g~~e. ~~Nurse~~ Authorized user identification; and ~~(3-21-12)~~( )

~~h~~f. Witness identification~~, if needed~~. ~~(3-21-12)~~( )

05. Supervising Pharmacy Identification. If used in a nursing home, the ADS system must be clearly marked with the name, address, and phone number of the supervising pharmacy and pharmacist-in-charge. (3-21-12)

293. VENDING MACHINES.
Only non-prescription medical supplies and drugs that are unrestricted for over-the-counter sale may be stored and sold in vending machines and are subject to inspection by the Board upon reasonable notice. ( )

292~~2~~4. -- 299. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

632. INSTITUTIONAL FACILITY: EMERGENCY DRUG SUPPLY PREPARATION AND MONITORING.
The director or PIC and the appropriate institutional facility personnel must jointly approve and develop a listing of drugs, by identity and quantity, for inclusion in an emergency cabinet, emergency kit, crash cart, or other similar resource that is specifically approved for use by that type of institutional facility and for delivery to patients receiving emergency treatment. In addition to other applicable provisions of these rules, approved drugs are subject to the following limitations, restrictions, and requirements: (3-21-12)

01. Prepackaged Amounts. The drugs must be prepackaged in amounts sufficient to satisfy immediate therapeutic requirements only, except when delivered in a hospital emergency room consistent with these rules; ~~(3-21-12)~~( )

02. Content Labeling. The drugs must be labeled as required by these rules for prepackaged products and with any additional information as may be required to prevent misunderstanding or risk of harm to patients; (3-21-12)

03. Access Documentation. Access to the emergency drugs must be documented by drug orders and, if applicable, proofs of use; (3-21-12)

04. Drug Expiration Monitoring. Drug expiration dates must be monitored and the drugs replaced as needed to ensure the emergency drug supply contains no outdated products; and (3-21-12)

05. Regular Inventory and Inspection. Emergency drug supplies must be regularly inventoried and inspected to ensure that they are properly stored and secured against pilferage or tampering. (3-21-12)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1204

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 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 17, 2012.

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:

To clarify the practice limitations of pharmacists and the members of a committee. To clarify that a pharmacist may order lab tests and substitute drug product in certain circumstances, but may not conduct physical examinations or engage in the practice of medicine; and to require that a pharmacist serve on a skilled nursing facility's quality assurance and assessment committee.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

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 Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 2, 2012 Idaho Administrative Bulletin, Vol. 12-5, Page 82, and in the August 1, 2012 Idaho Administrative Bulletin, Vol. 12-8, page 73, Docket No. 27-0101-1201.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 24, 2012.

DATED this 6th day of September, 2012.

Mark Johnston, R.Ph.
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Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1204

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. LTCF -- Long-Term Care Facility. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. MPJE. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

03. MTM -- Medication Therapy Management. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

04. NABP. National Association of Boards of Pharmacy. (3-21-12)

05. NAPLEX. North American Pharmacists Licensure Examination. (3-21-12)

06. NDC. National Drug Code. (3-21-12)

07. Non-Institutional Pharmacy. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

08. Parenteral Admixture. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

09. Pharmaceutical Care Services. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Except as permitted pursuant to a collaborative practice agreement, ~~N~~nothing in these rules allows a pharmacist, beyond what is statutorily allowed~~ *or allowed by a collaborative practice agreement*~~, to engage in the unlicensed practice of medicine or to diagnose, prescribe, ~~*order lab tests,*~~ or conduct ~~*complete*~~ physical examinations. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: ~~*(3-21-12)*~~( )

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; and (3-21-12)

m. Other services as allowed by law. (3-21-12)

10. Pharmacist Extern. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

11. Pharmacist Intern. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

12. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

13. PHI -- Protected Health Information. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)

14. PIC. Pharmacist-in-charge. (3-21-12)

15. **PMP**. Prescription Monitoring Program. (3-21-12)

16. **Prepackaging**. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)

17. **Prescriber**. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

18. **Prescriber Drug Outlet**. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

19. **Readily Retrievable**. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

20. **Relative Contraindication**. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

21. **Remote Dispensing Site**. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

22. **Retail Non-Pharmacy Drug Outlet**. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

23. **Retail Pharmacy**. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

24. **R.N**. Registered nurse. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

130. DRUG PRODUCT: SUBSTITUTION.
Drug product substitutions are allowed only ~~*in situations requiring compliance with*~~ as follows: ( )

01. **Hospital**. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; ~~*or*~~ ( )

02. **Skilled Nursing Facility**. At the direction of the quality assessment and assurance committee of a skilled nursing facility consisting of the director of nursing services, a physician designated by the facility, a consultant pharmacist, and at least ~~*three*~~ two (~~3~~2) other members of the facility's staff.; or ~~*(3-21-12)*~~( )

03. **Drug Shortage**. Upon a drug shortage, a pharmacist, using his best professional judgment, without contacting the prescriber, may substitute an alternative dose of a prescribed drug, so long as the prescriber's directions are also modified, to equate to an equivalent amount of drug dispensed as is prescribed. ( )

(BREAK IN CONTINUITY OF SECTIONS)

500. UNPROFESSIONAL CONDUCT.
The following acts or practices by a pharmacist, student pharmacist, or technician are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (3-21-12)

01. Unethical Conduct. Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (3-21-12)

02. Lack of Fitness. A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (3-21-12)

03. On-Duty Intoxication or Impairment. Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (3-21-12)

04. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (3-21-12)

05. Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (3-21-12)

06. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. ~~(3-21-12)~~( )

07. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (3-21-12)

08. Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (3-21-12)

09. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. The failure to retain appropriate documentation evidencing compliance with patient counseling requirements creates a rebuttable presumption of a violation of this rule. (3-21-12)

10. Substandard, Misbranded, or Adulterated Products. Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. (3-21-12)

11. Prescriber Incentives. Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (3-21-12)

12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (3-21-12)

13. Failure to Report. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (3-21-12)

14. Failure to Follow Board Order. Failure to follow an order of the Board. (3-21-12)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1205 (FEE RULE)

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 54-1717, 54-1720 and 54-1743, 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 17, 2012.

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:

Rural Idaho hospitals, as well as industry, have asked for more forms of the practice of pharmacy to be allowed into Idaho by nonresidents in order to improve public safety. As an example, more hospitals would be able to obtain "after hours" centralized pharmacy services when their own pharmacists are not on duty, increasing the speed and accuracy with which institutionalized patients receive new medications. The rulemaking expands the definition of central pharmacy to central drug outlet or pharmacist; expands the definition of centralized pharmacy services; moves an adapted definition of mail service pharmacy to rule; strikes a definition no longer used; expands and establishes criteria for the statutorily authorized pharmacist registration category; converts current out-of-state and across state lines drug outlet categories into an expanded nonresident drug outlet category and establishes registration criteria; defines when a pharmacist may be registered versus licensed; strikes extraneous language; requires all nonresident pharmacies and central drug outlets to register a PIC or director in Idaho; expands centralized pharmacy services practice standards; and reduces the requirements of a policy and procedures manual.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

The rulemaking establishes initial licensing ($500) and annual renewal ($250) fees for nonresident central drug outlets, pursuant to the authority in Sections 54-1720 and 54-1743, Idaho Code.

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:

Expected $150,000 additional annual income, however, the Board will assume addition licensing, registration, and investigational costs.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 2, 2012 Idaho Administrative Bulletin, Vol. 12-5, Page 82, and in the August 1, 2012 Idaho Administrative Bulletin, Vol. 12-8, page 73, Docket No. 27-0101-1201.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 24, 2012.

DATED this 5th day of September, 2012.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Telephone: (208) 334-2356
FAX: (208) 334-3536

THE FOLLOWING IS THE PROPOSED FEE TEXT FOR DOCKET NO. 27-0101-1205

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

01. Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)

02. ACPE. Accreditation Council for Pharmacy Education. (3-21-12)

03. Acute Care Hospital. A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)

04. ADS -- Automated Dispensing and Storage. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

05. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

06. Central ~~*Pharmacy*~~ Drug Outlet. A resident or nonresident pharmacy, ~~*within the state or a registered telepharmacy across state lines with which*~~ drug outlet or business entity employing or contracting pharmacists to perform centralized pharmacy services ~~*have been contracted*~~. ~~*(3-21-12)*~~( )

07. Central Pharmacist. A pharmacist performing centralized pharmacy services. ( )

08. Central Pharmacy. A pharmacy performing centralized pharmacy services. ( )

0~~7~~9. Centralized Pharmacy Services. The processing by a ~~*pharmacy*~~ central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, ~~*or to*~~ perform processing functions, ~~*such as prospective drug review*~~ or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations. ~~*(3-21-12)*~~( )

a. Intake includes all those processes involved in the receipt of the original prescription drug order at a pharmacy, as allowed by law. ( )

b. Processing means performing activities that may include, but are not limited to, prospective drug review, data entry, prescriber consultations, patient counseling, refill authorizations, and related services. ( )

c. Fulfillment involves manual filling or refilling the prescription drug order, including product selection, compounding, packaging, labeling, and otherwise preparing the prescription for delivery or administration to the patient. ( )

d. Dispensing involves the delivery of the filled or refilled prescription drug to the patient or the patient's representative, with counseling as required by law. ( )

e. Administrative services involve business administration and billing services, including data entry, claims submissions, claims resolution, claims adjudication, and related services. ( )

f. Pharmaceutical care services may be provided as needed or as required by law. ( )

~~08~~10. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)

~~09~~11. Charitable Clinic or Center -- Authorized Personnel. A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)

1~~0~~2. Chart Order. A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

1~~1~~3. CME. Continuing medical education. (3-21-12)

1~~2~~4. COE -- Central Order Entry. A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)

1~~3~~5. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

1~~4~~6. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

1~~5~~7. Continuous Quality Improvement Program. 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. (3-21-12)

1~~6~~8. CPE. Continuing pharmacy education. (3-21-12)

1~~7~~9. CPEU. Continuing pharmacy education unit. (3-21-12)

~~18~~20. DEA. United States Drug Enforcement Administration. (3-21-12)

~~19~~21. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

2~~0~~2. DME. Durable medical equipment. (3-21-12)

2~~1~~3. Drug Order. A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)

2~~2~~4. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

2~~3~~5. Drug Product Substitution. Dispensing a drug product other than prescribed without the express permission of the prescriber and patient. (3-21-12)

2~~4~~6. DTM -- Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

2~~5~~7. Emergency Drugs. Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)

2~~6~~8. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

2~~7~~9. FDA. United States Food and Drug Administration. (3-21-12)

~~28~~30. Flavoring Agent. An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)

~~29~~31. Floor Stock. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

3~~0~~2. HIPAA. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

3~~1~~3. Hospital System. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

3~~2~~4. Idaho State Board of Pharmacy or Idaho Board of Pharmacy. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (3-21-12)

3~~3~~5. Individually Identifiable Health Information. Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)

b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)

i. Identifies the individual; or (3-21-12)

ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)

~~34. Institution Engaged in The Practice of Telepharmacy Across State Lines. An institutional facility engaged in the practice of telepharmacy into Idaho that is an out-of-state hospital with an institutional pharmacy licensed or registered in another state or a COE pharmacy licensed or registered in another state that is part of a hospital system. (3-21-12)~~

3~~5~~6. Institutional Pharmacy. A pharmacy located in an institutional facility. (3-21-12)

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. LTCF -- Long-Term Care Facility. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. Mail Service Pharmacy. A nonresident pharmacy that ships, mails, or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law. ( )

0~~2~~3. MPJE. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

0~~3~~4. MTM -- Medication Therapy Management. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

0~~4~~5. NABP. National Association of Boards of Pharmacy. (3-21-12)

0~~5~~6. NAPLEX. North American Pharmacists Licensure Examination. (3-21-12)

0~~6~~7. NDC. National Drug Code. (3-21-12)

0~~7~~8. Non-Institutional Pharmacy. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

0~~8~~9. Parenteral Admixture. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

~~09~~10. Pharmaceutical Care Services. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Nothing in these rules allows a pharmacist, beyond what is statutorily allowed or allowed by a collaborative practice agreement, to diagnose, prescribe, order lab tests, or conduct complete physical exams. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (3-21-12)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; and (3-21-12)

m. Other services as allowed by law. (3-21-12)

10~~1~~. **Pharmacist Extern**. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

11~~2~~. **Pharmacist Intern**. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

12~~3~~. **Pharmacy Operations**. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

13~~4~~. **PHI -- Protected Health Information**. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)

14~~5~~. **PIC**. Pharmacist-in-charge. (3-21-12)

1~~5~~6. PMP. Prescription Monitoring Program. (3-21-12)

1~~6~~7. Prepackaging. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)

1~~7~~8. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

1~~8~~9. Prescriber Drug Outlet. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

~~19~~20. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

2~~0~~1. Relative Contraindication. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

2~~1~~2. Remote Dispensing Site. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

2~~2~~3. Retail Non-Pharmacy Drug Outlet. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

2~~3~~4. Retail Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

2~~4~~5. R.N. Registered nurse. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

021. FEE SCHEDULE.

01. Licenses -- Professionals. (3-21-12)

a. Original pharmacist license: one hundred dollars ($100). (3-21-12)

b. Licensure by reciprocity: two hundred fifty dollars ($250). (3-21-12)

c. Pharmacist license annual renewal. (3-21-12)

i. Active: ninety dollars ($90). (3-21-12)

ii. Inactive: fifty dollars ($50). (3-21-12)

d. Late payment processing: fifty dollars ($50). (3-21-12)

e. License reinstatement fee: seventy-five dollars ($75). (3-21-12)

02. Certificates of Registration -- Professionals. (3-21-12)

a. Pharmacist ~~*engaged in telepharmacy across state lines --*~~ registration or annual renewal: two hundred fifty dollars ($250). ~~*(3-21-12)*~~( )

b. Pharmacist intern - registration or annual renewal: fifty dollars ($50). (3-21-12)

c. Pharmacist extern registration and annual renewal: fifty dollars ($50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. (3-21-12)

d. Technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

e. Veterinary drug technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

f. Registration reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

03. Certificates of Registration and Licensure - Facilities. (3-21-12)

a. Retail pharmacy - registration or annual renewal: one hundred dollars ($100). (3-21-12)

b. Institutional facility - registration or annual renewal. (3-21-12)

i. Hospital pharmacy: one hundred dollars ($100). (3-21-12)

ii. Nursing home: thirty-five dollars ($35). (3-21-12)

iii. Hospital without a pharmacy: thirty-five dollars ($35). (3-21-12)

c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars ($100). (3-21-12)

d. Wholesaler. (3-21-12)

i. License or annual renewal: one hundred thirty dollars ($130); or (3-21-12)

ii. Registration or annual renewal: one hundred dollars ($100). (3-21-12)

e. Veterinary drug outlet - registration or annual renewal: one hundred dollars ($100). (3-21-12)

f. ~~*Telepharmacy across state lines - registration or annual renewal: one hundred dollars ($100) (3-21-12)*~~ Nonresident central drug outlet. ( )

i. Initial license: five hundred dollars ($500). ( )

ii. License annual renewal: two hundred fifty dollars ($250). ( )

g. Mail service pharmacy. (3-21-12)

i. Initial license: five hundred dollars ($500). (3-21-12)

ii. License annual renewal: two hundred fifty dollars ($250). (3-21-12)

h. Limited service outlet - registration or annual renewal. (3-21-12)

i. Limited service outlet, if not listed: one hundred dollars ($100). (3-21-12)

ii. Parenteral admixture pharmacy: one hundred dollars ($100). (3-21-12)

iii. Remote dispensing pharmacy: one hundred dollars ($100). (3-21-12)

iv. Facility operating a narcotic treatment program: one hundred dollars ($100). (3-21-12)

v. Durable medical equipment outlet: fifty dollars ($50). (3-21-12)

vi. Prescriber drug outlet: thirty five dollars ($35). (3-21-12)

i. Analytical or research lab -- registration or annual renewal: forty dollars ($40). (3-21-12)

j. Retail non-pharmacy outlets - registration or annual renewal. (3-21-12)

i. "A" (Stocks more than fifty (50) drug items): sixty dollars ($60). (3-21-12)

ii. "B" (Stocks fifty (50) or fewer drug items): twenty-five dollars ($25). (3-21-12)

iii. "V" (Vending machines): ten dollars ($10) per machine. (3-21-12)

k. Supplemental facility registrations or annual renewals. (3-21-12)

i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration required for one (1) or more hoods: no charge. (3-21-12)

ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)

l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

04. Controlled Substance Registration. (3-21-12)

a. Controlled substance - registration or annual renewal: sixty dollars ($60). (3-21-12)

b. Wholesaler or distributor controlled substance - registration or annual renewal: one hundred dollars ($100). (3-21-12)

c. Controlled substance registration reinstatement: seventy-five dollars ($75). (3-21-12)

05. Administrative Services and Publications. (3-21-12)

a. Experiential hours certification: twenty-five dollars ($25). (3-21-12)

b. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). (3-21-12)

c. Duplicate registration or license card: ten dollars ($10). (3-21-12)

d. Commercial lists. (3-21-12)

i. Pharmacy list: fifty dollars ($50). (3-21-12)

ii. Pharmacist list: fifty dollars ($50). (3-21-12)

iii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). (3-21-12)

e. Official Idaho Register: fifteen dollars ($15). (3-21-12)

f. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). (3-21-12)

g. Hearing transcript: five dollars ($5) per page. (3-21-12)

022. -- 02~~9~~8. (RESERVED)

029. PHARMACIST LICENSE OR REGISTRATION.

01. Practice in Idaho. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws and rules. ( )

02. Practice Into Idaho. All pharmacists practicing pharmacy into the state of Idaho must be licensed or registered as follows: ( )

a. The following pharmacists must be licensed to provide centralized pharmacy services into Idaho: ( )

i. Pharmacists engaged in the independent practice of pharmacy across state lines as defined by the Pharmacist Independent Practice Rule. ( )

ii. Pharmacists practicing from a central drug outlet that is not a pharmacy. ( )

b. The following pharmacists not licensed in Idaho must be registered to provide centralized pharmacy services into Idaho. ( )

i. The PIC of a nonresident central drug outlet or mail service pharmacy. ( )

ii. Pharmacists practicing from a pharmacy or its COE. ( )

(BREAK IN CONTINUITY OF SECTIONS)

035. PHARMACIST REGISTRATION ~~*FOR TELEPHARMACY ACROSS STATE LINES*~~ TO PRACTICE PHARMACY INTO IDAHO.
~~*A pharmacist not licensed*~~ To be registered to practice pharmacy into ~~*the state of*~~ Idaho an applicant must ~~*satisfy the requirements of Section 54-1723A, Idaho Code, and be registered*~~ submit an application in the manner and form prescribed by the Board including, but not limited to: ~~*lawfully engage in the practice of telepharmacy across state lines into the state of Idaho.*~~ ~~*(3-21-12)*~~( )

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; ( )

02. Facility License Information. The license or registration number of the facility from which the applicant will be practicing; and ( )

03. Attestation. An executed sworn statement attesting that the applicant will abide by the pharmacy laws and rules of the state of Idaho. ( )

(BREAK IN CONTINUITY OF SECTIONS)

060. DRUG OUTLET LICENSURE AND REGISTRATION.
A license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. (3-21-12)

01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location and the drug outlet may not open for business prior to satisfactory completion of the opening inspection, if required. (3-21-12)

02. Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. (3-21-12)

03. Reciprocity Nonresident Drug Outlet. The Board may license ~~*by reciprocity*~~ or register a drug outlet licensed or registered under the laws of another state if the other state's ~~*licensing*~~ standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report~~, and if the other state extends reciprocal licensure to Idaho drug outlets~~. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

071. ~~TELEPHARMACY AND~~ REMOTE DISPENSING SITE REGISTRATION.

~~***01. Telepharmacy Practice Registration.*** *Each location where drugs are dispensed through the practice of telepharmacy must be registered with the Board.* (3-21-12)~~

0~~2~~1. Remote Dispensing Site Registration. A limited service outlet registration must be obtained by a remote dispensing site prior to participating in the practice of telepharmacy. (3-21-12)

0~~3~~2. Supplemental Registration Application Requirements. Prior to construction, an applicant for registration of a remote dispensing site must submit and obtain Board approval of a registration application. The application must include: (3-21-12)

a. An attached description of the telepharmacy communication, electronic recordkeeping, and ADS systems; (3-21-12)

b. The operating specifications; and (3-21-12)

c. An accurate scale drawing of the facility that illustrates: (3-21-12)

i. The layout and location of the systems; (3-21-12)

ii. The location of a patient counseling area; and (3-21-12)

iii. All access points to the electronic recordkeeping system and the ADS system. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

073. NONRESIDENT CENTRAL DRUG OUTLET AND MAIL SERVICE PHARMACY REGISTRATION.
A nonresident central drug outlet or mail service pharmacy must be registered with the Board in order for its employee or contract pharmacist to practice pharmacy into Idaho. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: ( )

01. Executive Summary. An executive summary describing the centralized pharmacy services to be performed; ( )

02. PIC or Director. Identity of a pharmacist licensed to practice pharmacy in the state of domicile, who shall be the pharmacist in charge or director of the nonresident drug outlet. ( )

07~~3~~4. -- 079. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

090. MANUFACTURER REGISTRATION.
A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing. Non-resident manufacturers that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident must be registered by the Board as a~~n out-of state~~ mail service pharmacy~~ pursuant to 54-1743, Idaho Code~~. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

320. PHARMACIST: INDEPENDENT PRACTICE.
An Idaho-licensed pharmacist may provide pharmaceutical care services and MTM outside of a ~~pharmacy~~ drug outlet or institutional facility, including across state lines, if not subject to centralized pharmacy service rules and the following conditions are met: ~~(3-21-12)~~( )

01. Access to Relevant Information. The pharmacist has access to prescription drug order records, patient profiles, or other relevant medical information and appropriately reviews the information; (3-21-12)

02. Information Protected from Unauthorized Use. Access to the information required by these rules is protected from unauthorized access and use; and (3-21-12)

03. Records Maintained in Electronic Recordkeeping System. The pharmacist maintains the records or other patient-specific information created, collected, or used in an electronic recordkeeping system that complies with the requirements of these rules. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

600. ~~PHARMACY REGISTRANT AND~~ PIC OR DIRECTOR.

01. Designated PIC or Director Required. A pharmacy or central drug outlet must not be without a designated PIC or director for more than thirty (30) sequential days. ~~(3-21-12)~~( )

02. Corresponding and Individual Responsibility. The pharmacy ~~registrant~~ or central drug outlet and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

610. CENTRALIZED PHARMACY SERVICES.
A pharmacy may centralize pharmacy services if: ( )

01. Written Contract. The originating pharmacy has a written contract with the central drug outlet or central pharmacist outlining the services to be provided and the responsibilities and accountabilities of each party in

fulfilling the terms of the contract or the two (2) are jointly owned; ( )

02. Training. The central drug outlet or central pharmacist provides a training and orientation program that ensures the pharmacists who are providing centralized drug outlet services are competent to perform such services; ( )

03. Communication. Appropriate communications exist to allow the central drug outlet or central pharmacist to readily communicate with prescribers, the institutional facility, or the originating pharmacy; ( )

04. Secure Common Electronic File. The parties share a secure common electronic file or utilize other secure technology that allows access by the central drug outlet or central pharmacist to information required to perform centralized pharmacy services; ( )

05. Continuous Quality Improvement Program. The parties implement and maintain a quality improvement program designated to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; ( )

06. Audit Trail Documentation. The central drug outlet or central pharmacist maintains an electronic recordkeeping system that must have audit trail functionality that documents for each prescription drug order the identity and location of each individual involved in each step of the centralized pharmacy services; ( )

07. Privacy. The parties demonstrate adequate security to protect the privacy of PHI; ( )

08. Policies and Procedures. The parties adopt policies and procedures that are sufficiently detailed to ensure compliance with pertinent federal and Idaho law and protect public health, safety and welfare. ( )

09. Location. Centralized pharmacy services must be performed from a secure area that is restricted to authorized personnel and that provides adequate protection of PHI. ( )

10. Exemption. A single prescription drug order may be shared by an originating pharmacy and a central drug outlet or central pharmacist. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription or as a wholesale distribution. ( )

61~~0~~1. -- 619. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY.
A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance ~~*with these rules.*~~ as follows: ~~*(3-21-12)*~~( )

01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; ( )

02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; ( )

03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and ( )

04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. ( )

642. -- 649. (RESERVED)

650. INSTITUTIONAL FACILITY: CENTRALIZED PHARMACY SERVICES.
In addition to the rules for centralized pharmacy services, ~~A~~an institutional facility that centralizes pharmacy ~~*may centralize prescription drug order processing or filling services if*~~ services must be in compliance with the following rules: ~~(3-21-12)~~( )

01. Limited Purpose. ~~*The centralizing of prescription drug order processing or filling*~~ Centralized pharmacy services ~~*is*~~ are 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 if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; ~~(3-21-12)~~( )

~~***02. Institutional Facility Approval**. The originating pharmacy obtains approval from the institutional facility to centralize prescription drug order processing or filling services for its patients and residents; (3-21-12)***~~

~~***03. Written Contract**. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (3-21-12)***~~

~~***04. Drug or Chart Orders**. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. (3-21-12)***~~

~~***651. INSTITUTIONAL FACILITY: PRACTICE OF TELEPHARMACY.***~~

~~***01. Contracted Telepharmacy Services**. An institutional pharmacy may centralize pharmacy services through the practice of telepharmacy if: (3-21-12)***~~

~~***a.** The central pharmacy provides a training and orientation program that ensures that pharmacists who are providing telepharmacy services are competent to review and approve drug orders; (3-21-12)***~~

~~***b.** Appropriate video, telecommunications, or other systems allow the pharmacist within the central pharmacy to readily communicate with the prescribers within the institutional facility; (3-21-12)***~~

~~***c.** The parties share a common electronic file or utilize other technology that allows access by the central pharmacy to information required to fill or refill a prescription drug order; and (3-21-12)***~~

~~***d.** The parties implement and maintain a continuous quality improvement program for telepharmacy 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. (3-21-12)***~~

02. Policies and Procedures. An institutional pharmacy and its contracted central ~~*pharmacy*~~ drug outlet or central pharmacist that provides ~~*telepharmacy*~~ centralized pharmacy services must adopt policies and procedures and retain documentation that evidences at least the following: ~~(3-21-12)~~( )

~~***a.** A copy of the approval required by these rules; (3-21-12)***~~

~~***b**~~**a.** A copy of the contract if required by these rules; ~~(3-21-12)~~( )

~~***c**~~**b.** Identification of the directors ~~*of the central pharmacy and of the institutional pharmacy*~~ or PICs; ~~(3-21-12)~~( )

~~*d. The maintenance of appropriate records to identify the pharmacists providing centralized prescription drug order processing or filling services;* (3-21-12)~~

~~*e*~~c. The protocol for ensuring that the central ~~*pharmacy*~~ drug outlet maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; ~~(3-21-12)~~( )

~~*f. The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;* (3-21-12)~~

~~*g. The documentation and protocols demonstrating adequate security to protect the privacy of PHI;* (3-21-12)~~

~~*h*~~d. The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central ~~*pharmacy*~~ drug outlet or central pharmacist and for maintaining the security of the drugs; ~~(3-21-12)~~( )

~~*i*~~e. Essential information utilized by the institutional facility, such as its ~~*therapeutic interchange list,*~~ formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to the information; and ~~(3-21-12)~~( )

~~*j*~~f. The protocol for the central ~~*pharmacy*~~ drug outlet or central pharmacist to perform a review of the patient's profile, including but not limited to performing a prospective drug review. ~~(3-21-12)~~( )

65~~2~~1. -- 669. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

~~***680. TELEPHARMACY ACROSS STATE LINES.***~~
~~*The practice of telepharmacy across state lines is permitted only for institutions engaged in the practice of telepharmacy across state lines, as defined, and their pharmacists if both are registered or licensed as required by the Board.* (3-21-12)~~

68~~1~~0. -- 699. (RESERVED)