

# IDAHO BOARD OF PHARMACY

## 27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

### DOCKET NO. 27-0101-1402 (FEE RULE)

#### NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

**EFFECTIVE DATE:** This rule has been adopted by the agency and is now pending review by the 2015 Idaho State Legislature for final approval. The pending rule becomes final and effective at the conclusion of the legislative session, unless the rule is approved or rejected in part by concurrent resolution in accordance with Section 67-5224 and 67-5291, Idaho Code. If the pending rule is approved or rejected in part by concurrent resolution, the rule becomes final and effective upon adoption of the concurrent resolution or upon the date specified in the concurrent resolution.

**AUTHORITY:** In compliance with Section 67-5224, Idaho Code, notice is hereby given that this agency has adopted a pending rule. The action is authorized pursuant to Section 54-1717, Idaho Code.

**DESCRIPTIVE SUMMARY:** The following is a concise explanatory statement of the reasons for adopting the pending rule and a statement of any change between the text of the proposed rule and the text of the pending rule with an explanation of the reasons for the change.

This pending rule is needed to appropriately register a new class of drug outlet, recently created by the federal Drug Quality and Security Act. Changes in this pending language from the proposed language clarify that registration is only required when distributing drugs for human use and that rule 600 pertains to a PIC of an outsourcing facility too.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. Only those sections that have changes that differ from the proposed text are printed in this bulletin. The complete text of the proposed rule was published in the October 1, 2014 Idaho Administrative Bulletin, Vol. 14-10, pages 330 through 337.

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

This rulemaking is being promulgated due to the federal change that necessitates a state change and protects public safety by properly registering, including a registration fee, and instituting practice standards for outsourcing facilities. Pursuant to the board's authority set forth in Section 54-1720, Idaho Code, this rulemaking establishes fees for outsourcing facility registrations: five hundred dollar (\$500) initial nonresident registration; two hundred fifty dollar (\$250) initial resident registration; and two hundred fifty-dollar (\$250) registration annual renewal.

**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:

These rules will generate a small increase in the number of Board of Pharmacy registrants at either five hundred dollars (\$500) or two hundred fifty dollars (\$250) per initial registration and two hundred fifty dollars (\$250) per renewal. Currently the number of federally registered outsourcing facilities that are not already registered in another category appears to be three (3) — and the federal law has been in place since November of 2013.

**ASSISTANCE ON TECHNICAL QUESTIONS:** For assistance on technical questions concerning this pending rule, contact Mark Johnston, Executive Director, (208) 334-2356.

DATED this 28<sup>th</sup> day of November, 2014.

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

**DAPA 27  
TITLE 01  
CHAPTER 01**

**27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY**

**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. (7-1-13)

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

**04. 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)

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

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

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

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

**09. Outsourcing Drug Outlet.** A drug outlet that is registered by the United States Food and Drug Administration pursuant to 21 U.S.C. Section 353b and either registered or endorsed by the Board. ( )

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

**101. 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, nothing in these rules allows a pharmacist, beyond what is statutorily allowed, to engage in the unlicensed practice of medicine or to diagnose, prescribe, or conduct 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: (4-4-13)

- 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)

**142. Pharmacist Extern.** A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)

**123. 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)

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

**145. 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)
- 156.** **PIC.** Pharmacist-in-charge. (3-21-12)
- 167.** **PMP.** Prescription Monitoring Program. (3-21-12)
- 178.** **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)
- 189.** **Prescriber.** An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)
- 192.** **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)
- 201.** **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)
- 212.** **Relative Contraindication.** A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)
- 223.** **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)
- 234.** **Remote Office Location.** A secured area that is restricted to authorized personnel, adequately protects private health information, and shares a secure common electronic file or a private, encrypted connection with a pharmacy, from which a pharmacist who is contracted or employed by a central drug outlet performs centralized pharmacy services. (7-1-13)
- 245.** **Retail Non-Pharmacy Drug Outlet.** A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)
- 256.** **Retail Pharmacy.** A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)
- 267.** **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 registration or annual renewal: two hundred fifty dollars (\$250). (7-1-13)
- 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)
- 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. Nonresident central drug outlet. (7-1-13)
- i. Initial license: five hundred dollars (\$500). (7-1-13)
- ii. License annual renewal: two hundred fifty dollars (\$250). (7-1-13)
- 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)
<b>h.</b>	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.	Sterile product pharmacy: one hundred dollars (\$100).	(4-4-13)
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)
<u>vii.</u>	<u>Outsourcing facilities:</u>	(_____)
<u>(1)</u>	<u>Initial nonresident registration: five hundred dollars (\$500).</u>	(_____)
<u>(2)</u>	<u>Initial resident registration: two hundred fifty dollars (\$250).</u>	(_____)
<u>(3)</u>	<u>Registration annual renewal: two hundred fifty dollars (\$250).</u>	(_____)
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<b>i.</b>	Analytical or research lab -- registration or annual renewal: forty dollars (\$40).	(3-21-12)
<b>j.</b>	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)
<b>k.</b>	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)
<b>l.</b>	Reinstatement: one-half (1/2) the amount of the annual fee.	(3-21-12)
<b>04.</b>	<b>Controlled Substance Registration.</b>	(3-21-12)
<b>a.</b>	Controlled substance - registration or annual renewal: sixty dollars (\$60).	(3-21-12)
<b>b.</b>	Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars (\$100).	(3-21-12)
<b>c.</b>	Controlled substance registration reinstatement: seventy-five dollars (\$75).	(3-21-12)
<b>05.</b>	<b>Administrative Services and Publications.</b>	(3-21-12)
<b>a.</b>	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)*

**074. OUTSOURCING FACILITY REGISTRATION.**

An outsourcing facility must be registered with the Board in order to distribute compounded drug product for human use in or into Idaho. ( )

**01. Application.** An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: ( )

**a.** A copy of a valid FDA registration as an outsourcing facility as required by 21 U.S.C. Section 353b; ( )

**b.** Identity of a pharmacist licensed or registered in Idaho who is designated the PIC of the outsourcing facility; and ( )

**c.** An inspection report indicating compliance with applicable state and federal law. ( )

**02. Coincidental Activity.** An outsourcing facility applicant currently registered by the Board as a pharmacy or mail service pharmacy will be considered for an outsourcing facility registration with a supplemental pharmacy or mail service pharmacy registration at no additional fee. Exemption from registration fees does not excuse compliance with all laws and rules pertaining to pharmacies and mail service pharmacies. ( )

**0745. -- 079. (RESERVED)**

*(BREAK IN CONTINUITY OF SECTIONS)*

**600. PIC OR DIRECTOR.**

**01. Designated PIC or Director Required.** A new pharmacy, outsourcing facility, or central drug outlet must have a designated PIC or director by the date of opening and must not thereafter allow a vacancy or lapse in appointment of a designated PIC or director to continue for more than thirty (30) sequential days. (~~7-1-139-1-14T~~)

**02. Corresponding and Individual Responsibility.** The pharmacy, outsourcing facility, 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. (~~7-1-13~~)(9-1-14T)

**731. -- 7439. (RESERVED)**

**740. OUTSOURCING FACILITY.**

**01. Federal Act Compliance.** An outsourcing facility must ensure compliance with 21 U.S.C. Section 353b of the Federal Food, Drug and Cosmetic Act; (9-1-14)T

**02. Adverse Event Reports.** Outsourcing facilities shall submit a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with the content and format requirement established in Section 310.305 of Title 21 of the Code of Federal Regulations to the Board. ( )

**03. Policies and Procedures.** An outsourcing facility must adopt policies and procedures for maintaining records pertaining to compounding, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. ( )

**741. -- 749. (RESERVED)**