24.36.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; the Idaho Pharmacy Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act, Title 54, Chapter 17, Idaho Code; and specifically pursuant to Sections 37-2702, 37-2715, 54-1717, 54-1753, and 54-1755, Idaho Code. (3-28-23)

001. SCOPE.
These rules regulate and control the manufacture, distribution, and dispensing of controlled substances within or into the state, pursuant to the Uniform Controlled Substances Act, Section 37-2715, Idaho Code; and regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code. (3-28-23)

002. – 009. (RESERVED)

010. DEFINITIONS AND ABBREVIATIONS (A – N).
~~The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules.~~ ~~(3-28-23)~~

01. ACCME. Accreditation Council for Continuing Medical Education. (3-28-23)

02. ACPE. Accreditation Council for Pharmacy Education. (3-28-23)

03. 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. (3-28-23)

~~**04. Change of Ownership**. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board.~~ ~~(3-28-23)~~

05. CME. Continuing medical education. (3-28-23)

06. CPE. Continuing pharmacy education. (3-28-23)

07. CPE Monitor. An NABP service that allows pharmacists to electronically keep track of CPE credits from ACPE-accredited providers. (3-28-23)

08. DEA. United States Drug Enforcement Administration. (3-28-23)

09. DME Outlet. A registered outlet that may hold for sale at retail durable medical equipment (DME) and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection. (3-28-23)

10. Drug Outlet. Drug outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, DME outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, mobile pharmacies, and analytical or research laboratories.(3-28-23)

11. FDA. United States Food and Drug Administration. (3-28-23)

12. Flavoring Agent. An additive in food or drugs in the minimum quantity necessary. (3-28-23)

13. 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. (3-28-23)

Commented [RS1]: Separate Definitions and Abbreviations.

Commented [RS2]: Probably superfluous.

Commented [RS3]: Is this definition necessary, or is "Automated Dispensing and Storage" already understood such that we could replace this definition with a definition of the abbreviation: "ADS. Automated dispensing and storage."

Commented [RS4]: Definition uses term to define itself, so superfluous.

Commented [RS5]: Only used once in Rule 213.01. Is this a necessary definition? If so, could it be incorporated into that section?

Commented [RS6]: Should DME be a defined abbreviation?

Commented [RS7]: Only used in the next definition; is there a way to combine these?

Commented [RS8]: Drug outlet is defined in 54-1705(16). This is not really a definition, but a list of examples of drug outlets, not inconsistent with the statutory definition. Could this section be incorporated into current Rule 300?

Commented [RS9]: Only used in Rule 700.01(d); work definition into that section.

Commented [RS10]: Only used in Rule 303; can we work this definition into that section?

14. **FPGEC Certification**. Foreign Pharmacy Graduate Examination Committee Certification. (3-28-23)

15. **Hazardous Drug**. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: carcinogenicity; teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low doses in humans or animals; genotoxicity; or new drugs that mimic existing hazardous drugs in structure or toxicity. (3-28-23)

16. **HIPAA**. Health Insurance Portability and Accountability Act of 1996. (3-28-23)

17. **NABP**. National Association of Boards of Pharmacy. (3-28-23)

18. **NAPLEX**. North American Pharmacists Licensure Examination. (3-28-23)

19. **NDC**. National Drug Code. (3-28-23)

011. DEFINITIONS AND ABBREVIATIONS (O – Z).

~~The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms have the meanings set forth below:~~ ~~(3-28-23)~~

01. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. (3-28-23)

02. **Pharmaceutical Care Services**. Pharmaceutical care services include a~~A~~ broad range of services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients ~~consistent with Rule 100~~. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and also encompasses services provided by way of DTM under a collaborative practice agreement. Pharmaceutical care services are not limited to, but may include one (1) or more of the following: (3-28-23)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities or testing; (3-28-23)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-28-23)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-28-23)

d. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; (3-28-23)

e. Ordering and interpreting laboratory tests; (3-28-23)

f. Performing drug product selection, substitution, prescription adaptation, or refill authorization as provided in these rules; and (3-28-23)

g. Prescribing drugs and devices as provided in these rules. (3-28-23)

03. **PDMP**. Prescription Drug Monitoring Program. (3-28-23)

~~**04.** **Prescriber**. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-28-23)~~

05. **Purple Book**. The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. (3-28-23)

Commented [RS11]: Superfluous.

Commented [RS12]: Only used in Rule 406.02. Can this definition be worked into that rule?

Commented [RS13]: DTM is not a defined abbreviation; we may need to add that definition.

Commented [RS14]: Move to Practice Standards.

Commented [RS15]: Duplicative of I.C. 54-1705(51).

Commented [RS16]: The FDA's Purple Book probably doesn't need to be defined; well understood within pharmacy. And it's only used once below in Rule 404.03.

06. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-28-23)

07. Reconstitution. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. (3-28-23)

08. Restricted Drug Storage Area. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-28-23)

09. 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~~)~~. (3-28-23)

10. USP-NF. United State Pharmacopeia-National Formulary. (3-28-23)

012. – 099. (RESERVED)

SUBCHAPTER A – GENERAL PROVISIONS
(Rules 100 through 199)

100. PRACTICE OF PHARMACY: GENERAL APPROACH.
To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, or whether an act can be delegated to other individuals under their supervision, a licensee or registrant of the Board must independently determine whether: (3-28-23)

01. Express Prohibition. The act is expressly prohibited by: (3-28-23)

a. The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code; (3-28-23)

b. The Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; (3-28-23)

c. The rules of the Idaho State Board of Pharmacy; or (3-28-23)

d. Any other applicable state or federal laws or regulations. (3-28-23)

02. Education, Training, and Experience. The act is consistent with licensee or registrant's education, training, and experience. (3-28-23)

03. Standard of Care. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience. (3-28-23)

101. PRESCRIBER PERFORMANCE OF PHARMACY FUNCTIONS.
For the purposes of this chapter, any function that a pharmacist may perform may similarly be performed by an Idaho prescriber or may be delegated by an Idaho prescriber to appropriate support personnel, in accordance with the prescriber's practice act. (3-28-23)

102. WAIVERS OR VARIANCES.

01. Emergency Waiver. In the event of an emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, the division administrator may waive any requirement of these rules for the duration of the emergency. (3-28-23)

Commented [RS17]: Only used once in Rule 700.01(c); could this definition be incorporated into that section?

Commented [RS18]: Only used once in 300.03; could this definition be incorporated into that section?

Commented [RS19]: Only used once in Rule 402.01. Because the Orange Book and Green Book are well understood terms in pharmacy, could this be condensed and incorporated into that section?

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103. BOARD INSPECTIONS AND INVESTIGATIONS.

01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (3-28-23)

02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (3-28-23)

03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (3-28-23)

04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (3-28-23)

05. Investigations. Licensees or registrants must fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, to gather information pertinent to a complaint received by the Board, or to enforce disciplinary actions. (3-28-23)

104. UNPROFESSIONAL CONDUCT.
The following acts or practices by any licensee or registrant are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

08. Excessive Provision of Controlled Substances. Providing an 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). (3-28-23)

09. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. (3-28-23)

10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock. (3-28-23)

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. (3-28-23)

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. (3-28-23)

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. (3-28-23)

14. Failure to Follow Board Order. Failure to follow an order of the Board. (3-28-23)

15. Use of False Information. Knowingly using false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product. (3-28-23)

16. Standard of Care. Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting. (3-28-23)

17. Unnecessary Services or Products. Directly promoting or inducing for the provisions of health care services or products that are unnecessary or not medically indicated. (3-28-23)

18. Controlled Substance Non-Compliance. Violating provisions of the federal Controlled Substances Act or Title 37, Chapter 27, Idaho Code. (3-28-23)

105. – 199. (RESERVED)

SUBCHAPTER B – RULES GOVERNING LICENSURE AND REGISTRATION
(Rules 200 through 299)

200. BOARD OF PHARMACY LICENSURE AND REGISTRATION.

~~The Board will issue or renew a license or certificate of registration upon application and determination that the applicant has satisfied the requirements of applicable statutes, and any additional criteria specified by these rules. Licenses or registrations must be obtained prior to engaging in these practices or their supportive functions.~~ ~~(3-28-23)~~

Commented [RS20]: Covered by 54-1718 and 54-1721.

201. LICENSURE AND REGISTRATION: GENERAL REQUIREMENTS.

~~**01. Board Forms**. Initial applications, annual renewal applications, and other forms used for licensure, registration, or other purposes must be in such form as designated by the Board.~~ ~~(3-28-23)~~

Commented [RS21]: Duplicative of 54-1722, 54-1723, 54-1723A, 54-1729.

02. Incomplete Applications. Information requested on any form must be provided and submitted to the Board office with the applicable fee or the submission will be considered incomplete and will not be processed.

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Applications that remain incomplete after six (6) months from the date of initial submission will expire. (3-28-23)

03. On-Time Annual Renewal Application. Licenses and registrations must be renewed annually prior to expiration to remain valid. Timely submission of the renewal application is the responsibility of each licensee or registrant. Licenses and certificates of registration issued to individuals will expire annually on the last day of the individual's birth month, and on December 31 for facilities, unless an alternate expiration term or date is stated in these rules. (3-28-23)

04. Late Renewal Application. Failure to submit a renewal application prior to the expiration date will cause the license or registration to lapse and will result in the assessment of a late fee and possible disciplinary action. A lapsed license or registration is invalid until renewal is approved by the Board and if not renewed within thirty (30) days after its expiration will require reinstatement. (3-28-23)

05. Exemption. New licenses and registrations issued ten (10) weeks or less prior to the renewal due date are exempt from the renewal requirements that year only. (3-28-23)

06. Cancellation and Registration. Failure to maintain the requirements for any registration will result in the cancellation of the registration. (3-28-23)

07. Reinstatement of License or Registration. Unless otherwise specified in Board rule, consideration of a request for reinstatement of a license or registration will require a completed application on a Board form, submission of a completed fingerprint card, as applicable, and payment of any applicable fees due or delinquent at the time reinstatement is requested. (3-28-23)

08. Parent or Legal Guardian Consent. No person under the age of eighteen (18), unless an emancipated minor, may submit an application for licensure or registration without first providing the Board with written consent from a parent or legal guardian. (3-28-23)

202. BOARD FEES.

01. Fee Determination and Collection. Pursuant to the authority and limitations established by Sections 37-2715 and 54-1720(5)(a), Idaho Code, the Board has determined and will collect fees for the issuance, annual renewal, or reinstatement of licenses and certificates of registration to persons and drug outlets engaged in acts or practices regulated by the Board. (3-28-23)

02. Time and Method of Payment. Fees are due at the time of application payable to the "Idaho State Board of Pharmacy." (3-28-23)

03. Fee for Dishonored Payment. A reasonable administrative fee may be charged for a dishonored check or other form of payment. If a license or registration application has been approved or renewed by the Board and payment is subsequently dishonored, the approval or renewal is immediately canceled on the basis of the submission of an incomplete application. The board may require subsequent payments to be made by cashier's check, money order, or other form of guaranteed funds. (3-28-23)

04. Fee Exemption for Controlled Substance Registrations. Persons exempt pursuant to federal law from fee requirements applicable to controlled substance registrations issued by the DEA are also exempt from fees applicable to controlled substance registrations issued by the Board. (3-28-23)

203. FEE SCHEDULE.

01. Licenses and Registrations – Professionals.

License/Registration	Initial Fee	Annual Renewal Fee
Pharmacist License	$140	$130

Commented [RS22]: Covered by 54-1723A, but only for certificants practicing into Idaho.

Commented [RS23]: Duplicative of 54-1729. If the section is kept, this language should probably be kept to avoid confusion.

Commented [RS24]: This may be superseded by the licensing renewal EAL.

Commented [RS25]: Appears duplicative of 54-1718(2) and 54-1728(7).

Commented [RS26]: Why?

Nonresident PIC Registration	$290	$290
Pharmacist Intern	$50	$50
Technician	$35	$35
Practitioner Controlled Substance Registration	$60	$60

(3-28-23)

Commented [RS27]: This fee is waivable; can that be called out?

02. Certificates of Registration and Licensure – Facilities.

License/Registration	Initial Fee	Annual Renewal Fee
Drug Outlet (unless otherwise listed)	$100	$100
Wholesale License	$180	$180
Wholesale Registration	$150	$150
Central Drug Outlet (Nonresident)	$500	$250
Mail Service Pharmacy	$500	$250
Durable Medical Equipment Outlet	$50	$50
Outsourcing Facility (Nonresident)	$500	$250
Manufacturer	$150	$150
Veterinary Drug Outlet	$35	$35

(3-28-23)

03. Late Fees and Reinstatements.

Category	Fee
Late payment processing fee	$50
License or registration reinstatement fee	One-half (1/2) of the amount of the annual renewal

(3-28-23)

04. Administrative Services.

Category	Fee
Experiential hours certification	$25
Duplicate pharmacist certificate of licensure	$35

(3-28-23)

204. – 209. (RESERVED)

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210. DETERMINATION OF NEED FOR NONRESIDENT LICENSURE OR REGISTRATION.

01. Independent Practice. Nonresident pharmacists must be licensed if engaged in the independent practice of pharmacy across state lines and not practicing for an Idaho registered drug outlet. (3-28-23)

02. Practice for an Idaho Registered Drug Outlet. A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho. All other nonresident pharmacists who are employed by, or affiliated with, and practicing for the Idaho registered nonresident drug outlet, but who are not the PIC, are exempt from license and registration requirements for practice into Idaho. (3-28-23)

03. Multistate Pharmacists. Multistate pharmacists, as defined in Section 54-1723B, Idaho Code, are exempt from separate licensure or registration in Idaho. (3-28-23)

04. Exemption from Separate Controlled Substance Registration. All pharmacists who are practicing in or into Idaho are exempt from obtaining a separate controlled substance registration, but are subject to compliance with all requirements under Title 37, Chapter 27, Idaho Code. (3-28-23)

211. PHARMACIST LICENSURE BY EXAMINATION.

To be considered for licensure, a person must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, submit to the Board an application for licensure by examination, and meet the following: (3-28-23)

01. Graduates of U.S. Pharmacy Schools. Graduate from an ACPE-accredited school or college of pharmacy within the United States. (3-28-23)

02. Graduates of Foreign Pharmacy Schools. Graduate from a school or college of pharmacy located outside of the United States, submit certification by the FPGEC, and complete a minimum of seventeen hundred forty (1,740) experiential hours as verified on an employer's affidavit signed by a pharmacist licensed and practicing in the United States. The Board may request verifiable business records to document the hours. (3-28-23)

03. Licensure Examinations. Qualified applicants must pass the NAPLEX in accordance with NABP standards. A candidate who fails the NAPLEX three (3) times must complete at least thirty (30) hours of continuing education accredited by an ACPE-accredited provider prior to being eligible to sit for each subsequent reexamination. Candidates are limited to five (5) total NAPLEX attempts. (3-28-23)

04. Score Transfer. Score transfers into Idaho during the examination registration process are accepted for one (1) year. After taking the exam, score transfers into Idaho must be submitted within eighty-nine (89) days. (3-28-23)

212. PHARMACIST LICENSURE BY RECIPROCITY.

An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and submit a preliminary application for licensure transfer through NABP. An applicant whose pharmacist license is currently restricted by a licensing entity in another state must appear before the Board to petition for licensure by reciprocity. An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may have to complete intern hours for each year away from the practice of pharmacy. (3-28-23)

213. PHARMACIST LICENSE: CPE REQUIREMENTS.

Each pharmacist must complete fifteen (15) CPE hours each calendar year between January 1 and December 31. (3-28-23)

01. ACPE. At least twelve (12) of the CPE hours obtained must be from programs by an ACPE that have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ACPE credits must be reported to and documented in CPE Monitor in order to be accepted. (3-28-23)

02. CME. A maximum of three (3) of the hours may be obtained from CME, if the credits are:

(3-28-23)

a. Obtained from an ACCME accredited provider; and (3-28-23)

b. A certificate is furnished that identifies the name of the ACCME accredited provider and a clear reference to its accreditation status, the title of the CME program, the completed hours of instruction, the date of completion, and the name of the individual obtaining the credit. Upon audit, all CME certificates must be submitted to the Board. (3-28-23)

03. Alternative to CPE. If audited, a pharmacist may substitute a current certification by a nationally accredited pharmacy practice-specific specialty certification program. (3-28-23)

214. PHARMACIST LICENSE: REINSTATEMENT.
The Board may, at its discretion, consider reinstatement of a pharmacist license upon receipt of a completed application, background check, and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested. (3-28-23)

01. Satisfactory Evidence. Reinstatement applicants must provide satisfactory evidence of completion of a minimum of thirty (30) CPE hours within the twenty-four (24) months prior to reinstatement and compliance with any direct orders of the Board. (3-28-23)

02. Additional Requirements. A pharmacist reinstatement applicant 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 intern hours, completion of additional CPE hours, or other requirements determined necessary to acquire or demonstrate professional competency. (3-28-23)

215. NONRESIDENT PIC REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered as a nonresident PIC, an applicant must submit an application on a Board form including, but not limited to: (3-28-23)

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (3-28-23)

02. Facility License Information. The license or registration number of the facility for which the applicant will be practicing. (3-28-23)

216. PHARMACIST INTERN REGISTRATION.

01. Registration Requirements. To be approved for and maintain registration as a pharmacist intern, the applicant must: (3-28-23)

a. Currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy; or (3-28-23)

b. Be a graduate of an accredited school or college of pharmacy within the United States and awaiting examination for pharmacist licensure; or (3-28-23)

c. Be a graduate of a school or college of pharmacy located outside the United States, obtain certification by the FPGEC, and be awaiting finalization of pharmacist licensure. (3-28-23)

02. Renewal. (3-28-23)

a. Current Students. A pharmacist intern registration must be renewed annually by July 15; however, the renewal fee will be waived, if renewed on time, for the duration of the student's enrollment in the school or college of pharmacy. Following graduation, if a pharmacist license application has been submitted, the pharmacist

intern license will be extended at no cost for up to six (6) additional months from the date of application as a

pharmacist, after which time the individual will need to submit a new application to continue to be a pharmacist intern. (3-28-23)

b. Pharmacy Graduates. A graduate pharmacist intern registration may be obtained and renewed once within one (1) year from the date of issuance. The Board may, at its discretion, grant additional time to complete internship experience if unique circumstances present. (3-28-23)

217. – 219. (RESERVED)

220. TECHNICIAN REGISTRATION.

01. Registration Requirements. A person may apply for registration as a technician if the person satisfies the following requirements: (3-28-23)

a. Age. Be at least sixteen (16) years of age. (3-28-23)

b. Exemption from Criminal Background Check. Technician candidates under the age of eighteen (18) are exempt from the fingerprint-based criminal history check requirement of Idaho Code. (3-28-23)

02. Certified Technician Registration. To be approved for registration as a certified technician, a person must have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the National Healthcareer Association (NHA), or their successors. (3-28-23)

221. – 223. (RESERVED)

224. PRACTITIONER CONTROLLED SUBSTANCE REGISTRATION.
Any practitioner in Idaho who intends to prescribe, administer, dispense, or conduct research with a controlled substance must first obtain an Idaho practitioner controlled substance registration and: (3-28-23)

01. State License. Hold a valid license or registration to prescribe medications from a licensing entity established under Title 54, Idaho Code. (3-28-23)

02. DEA Registration. Obtain a valid federal DEA registration, if needed under federal law. (3-28-23)

a. Failure to obtain a federal DEA registration for any reason within forty-five (45) days of the issuance of the Idaho Practitioner Controlled Substance Registration will result in automatic cancellation. (3-28-23)

225. – 229. (RESERVED)

230. DRUG OUTLET LICENSURE AND REGISTRATION: GENERAL REQUIREMENTS.
A license or a certificate of registration is required for drug outlets prior to 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. (3-28-23)

01. New Drug Outlet Inspections. Following the issuance of a new license or registration, each drug outlet will be inspected to confirm that the facility is compliant with applicable law. A change of ownership of a currently registered pharmacy will not require an onsite inspection of a new pharmacy registration unless a change of location occurs. (3-28-23)

02. License and Registration Transferability. Drug outlet licenses and registrations are location and owner specific and are nontransferable as to person or place. (3-28-23)

03. Nonresident Drug Outlet. The Board may license or register a drug outlet licensed or registered

under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. (3-28-23)

04. Change of Location. At least ten (10) days prior to the event, the registrant must notify the Board of a drug outlet's change of location through the completion of an application for a new license or registration. When a licensee or registrant has made a timely and complete application for a new license or registration, the existing license does not expire until the application has been finally determined by the Board, and, in case the application is denied or the terms of the new license limited, until the last day for seeking review of the Board order. This does not preclude the Board from taking immediate action to protect the public interest. (3-28-23)

05. Change of Ownership. The registrant must notify the Board of a drug outlet's change of ownership within thirty (30) days of the event on a Board form. (3-28-23)

06. Permanent Closing. A registrant must notify the Board and the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the proposed date of closure, and the new location of the prescription files. The notice to the board is to include the location where the closing inventory record of controlled substances is retained. (3-28-23)

07. Exemption from Separate Controlled Substance Registration. All drug outlets doing business in or into Idaho who hold a valid license or registration from the Board are exempt from obtaining a separate controlled substance registration, but are subject to compliance with all requirements under Title 37, Chapter 27, Idaho Code. (3-28-23)

08. Sterile Preparation Endorsement. A drug outlet engaged in sterile preparation must obtain a single endorsement for one (1) or more hood or aseptic environmental control devices. (3-28-23)

231. -- 239. (RESERVED)

240. WHOLESALER LICENSURE AND REGISTRATION.

01. Wholesaler Licensure. The following information must be provided under oath by each applicant for wholesaler licensure as part of the initial licensing procedure and for each renewal on a Board form: (3-28-23)

a. Any felony conviction or any conviction of the applicant relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-28-23)

b. Any discipline of the applicant by a regulatory agency in any state for violating any law relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-28-23)

02. NABP Accreditation. The Board will recognize a wholesaler's accreditation by NABP for purposes of reciprocity and satisfying the new drug outlet inspection requirements of these rules. (3-28-23)

03. Wholesaler Registration. Except when licensed pursuant to the Idaho Wholesale Drug Distribution Act and these rules, a wholesaler that engages in wholesale distribution of DME supplies, prescription medical devices, or products that contain pseudoephedrine in or into Idaho must be registered by the Board. (3-28-23)

241. – 249. (RESERVED)

250. MANUFACTURER REGISTRATION.
Manufacturers must be registered as follows: (3-28-23)

01. Mail Service Pharmacy. Those that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident will be registered by the Board as a mail service pharmacy. (3-28-23)

02. Manufacturer. Those engaged in wholesale distribution will be registered as a manufacturer and comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. (3-28-23)

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251. – 299. (RESERVED)

SUBCHAPTER C – DRUG OUTLET PRACTICE STANDARDS

(Rules 300 through 399)

300. DRUG OUTLETS: MINIMUM FACILITY STANDARDS.
A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: (3-28-23)

01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (3-28-23)

02. Controlled Substance Storage. Drug outlets must store controlled substances in accordance with federal law. (3-28-23)

03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (3-28-23)

04. Staffing. A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business. (3-28-23)

05. Electronic Recordkeeping System. A drug outlet that dispenses more than twenty (20) prescriptions per day must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. The electronic recordkeeping system must have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes. (3-28-23)

301. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM PRESCRIPTION FILLING REQUIREMENTS.
Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements either at the drug outlet or through offsite pharmacy services: (3-28-23)

01. Valid Prescription Drug Order. Prescription drugs may only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter E of these rules. (3-28-23)

02. Prospective Drug Review. Prospective drug review must be provided. (3-28-23)

03. Labeling. Each drug must bear a complete and accurate label as set forth in these rules. (3-28-23)

04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. A compounded drug may only be verified by a pharmacist or prescriber. (3-28-23)

05. Patient Counseling. Counseling must be provided. (3-28-23)

302. DRUG OUTLETS THAT DISPENSE DRUGS TO PATIENTS WITHOUT AN ONSITE PHARMACIST OR PRESCRIBER.
A drug outlet that dispenses drugs to patients in Idaho that does not have a pharmacist or prescriber onsite to perform or supervise pharmacy operations must comply with the following requirements: (3-28-23)

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01. Security and Access. Maintain adequate video surveillance of the facility and retain a high quality recording for a minimum of thirty (30) days. (3-28-23)

02. Technology. The video or audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. (3-28-23)

03. Technical Limitation Closure. The drug outlet must be, or remain, closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, until system corrections or repairs are completed. (3-28-23)

04. Exemption for Self-Service Systems. A self-service ADS that is operating as a drug outlet is exempt from the video surveillance requirement and the self-inspection requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADS is exempt from the video and audio communication system requirements of this rule. (3-28-23)

05. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act are exempt from this rule. (3-28-23)

303. DRUGS STORED OUTSIDE OF A DRUG OUTLET FOR RETRIEVAL BY A LICENSED HEALTH PROFESSIONAL.

Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: (3-28-23)

01. Supervising Drug Outlet. Drugs stored in such a manner must remain under the control of, and be routinely monitored by, the supervising drug outlet. (3-28-23)

02. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. (3-28-23)

03. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. (3-28-23)

04. Stocking and Replenishing. Stocking or replenishing drugs in an alternative designated area may be performed by a pharmacist or prescriber, or by appropriate support personnel using either an electronic verification system or a two (2) person checking system. (3-28-23)

304. – 349. (RESERVED)

SUBCHAPTER D – RULES GOVERNING PHARMACIST PRESCRIPTIVE AUTHORITY
(Rules 350 through 399)

350. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.

In accordance with Section 54-1705, Idaho Code, a pharmacist may independently prescribe provided the following general requirements are met by the pharmacist: (3-28-23)

01. Education. Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained. (3-28-23)

02. Patient-Prescriber Relationship. Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code. (3-28-23)

03. Patient Assessment. Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. (3-28-23)

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04. Collaboration with Other Health Care Professionals. Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate. (3-28-23)

05. Documentation. Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan. (3-28-23)

06. Prescribing Exemption. The general requirements set forth in this section do not apply to collaborative pharmacy practice agreements, devices, and nonprescription drugs. (3-28-23)

351. COLLABORATIVE PHARMACY PRACTICE.
Collaborative pharmacy practice may be performed in accordance with an agreement that identifies the parties to the agreement, the pharmacist's scope of practice authorized, and if necessary, any monitoring parameters. (3-28-23)

352. -- 399. (RESERVED)

SUBCHAPTER E – FILLING AND DISPENSING PRESCRIPTION DRUGS
(Rules 400 through 499)

400. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. (3-28-23)

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued by a licensed prescriber for a legitimate medical purpose, and within the course and scope of the prescriber's professional practice and prescriptive authority. (3-28-23)

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. (3-28-23)

03. Tampering. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. (3-28-23)

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (3-28-23)

05. Digital Image Prescriptions. A digital image of a prescription drug order is invalid if it is for a controlled substance or if the patient intends to pay cash for the drug in whole. (3-28-23)

401. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.
A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, include at least the following: (3-28-23)

01. Patient's Name. The patient's or authorized entity's name and: (3-28-23)

a. If for a controlled substance, the patient's full name and address; and (3-28-23)

b. If for an animal, the species. (3-28-23)

02. Date. The date issued. (3-28-23)

03. Drug Information. The drug name, strength, and quantity. (3-28-23)

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04. **Directions**. The directions for use. (3-28-23)

05. **Prescriber Information**. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (3-28-23)

06. **Signature**. A signature sufficient to evidence a valid prescription of either the prescriber or, if a renewal of a previous prescription, the prescriber's agent, when authorized by the prescriber. (3-28-23)

07. **Institutional Drug Order Exemptions**. An institutional drug order may exempt the patient's address, the dosage form, quantity, prescriber's address, and prescriber's DEA registration number. (3-28-23)

08. **Exemptions for Non-Controlled Substances**. A prescriber may omit drug information and directions and make an indication for the pharmacist to finalize the patient's drug therapy plan. (3-28-23)

402. FILLING PRESCRIPTION DRUG ORDERS: PRACTICE LIMITATIONS.

01. **Drug Product Selection**. Drug product selection is allowed only between therapeutic equivalent drugs. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug product selection is permitted. (3-28-23)

02. **Partial Filling**. A prescription drug order may be partially filled within the limits of federal law. The total quantity dispensed in partial fillings must not exceed the total quantity prescribed. (3-28-23)

03. **Refill Authorization**. A prescription drug order may be refilled when permitted by state and federal law and as specifically authorized by the prescriber. A pharmacist may also refill a prescription for a non-controlled drug to ensure continuity of care. (3-28-23)

403. FILLING PRESCRIPTION DRUG ORDERS: ADAPTATION.
A pharmacist may adapt drugs as specified in this rule. (3-28-23)

01. **Change Quantity**. A pharmacist may change the quantity of medication prescribed if: (3-28-23)

a. The prescribed quantity or package size is not commercially available; (3-28-23)

b. The change in quantity is related to a change in dosage form, strength, or therapeutic interchange; (3-28-23)

c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or (3-28-23)

d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. (3-28-23)

02. **Change Dosage Form**. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. (3-28-23)

03. **Complete Missing Information**. A pharmacist may complete missing information on a prescription if there is evidence to support the change. (3-28-23)

04. **Documentation**. The adaption must be documented in the patient's record. (3-28-23)

404. FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION.
Drug product substitutions in which a pharmacist dispenses a drug product other than that prescribed are allowed only as follows: (3-28-23)

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01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (3-28-23)

02. Institutional Facility. At the direction of the quality assessment and assurance committee of an institutional facility; (3-28-23)

03. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (3-28-23)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (3-28-23)

b. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (3-28-23)

04. Therapeutic Interchange. A pharmacist may substitute a drug with another drug in the same therapeutic class, provided the substitution lowers the cost to the patient or occurs during a drug shortage. (3-28-23)

405. FILLING PRESCRIPTION DRUG ORDERS: TRANSFERS.

A prescription drug order may be transferred within the limits of federal law. Drug outlets using a common electronic file are exempt from transfer limits. (3-28-23)

406. LABELING STANDARDS.

All prescription drugs must be in an appropriate container and bear information that identifies the drug product, any additional components as appropriate, and the individual responsible for its final preparation. (3-28-23)

01. Standard Prescription Drug. A prescription drug for outpatient dispensing must be labeled in accordance with federal law. (3-28-23)

02. Parenteral Admixture. If one (1) or more drugs are added to a parenteral admixture, the admixture's container must include the date and time of the addition, or alternatively, the beyond use date. (3-28-23)

03. Prepackaged Product. The containers of prepackaged drugs must include an expiration date that is the lesser of the manufacturer's original expiration date, one (1) year from the date the drug is prepackaged, or a shorter period if warranted. (3-28-23)

04. Repackaged Drug. If a previously dispensed drug is repackaged, it must contain the serial number and contact information for the original dispensing pharmacy, as well as a statement that indicates that the drug has been repackaged, and the contact information of the repackaging pharmacy. (3-28-23)

05. Distributed Compounded Drug Product. Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription must be labeled as follows: (3-28-23)

a. If from a pharmacy, the statement: “not for further dispensing or distribution.” (3-28-23)

b. If from an outsourcing facility, the statements: “office use only” and “not for resale.” (3-28-23)

407. PRESCRIPTION DELIVERY: RESTRICTIONS.

01. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions in accordance with federal law, as long as appropriate measures are taken to ensure product integrity and safety. (3-28-23)

02. Pick-up or Return by Authorized Personnel. Filled prescriptions may be picked up for or returned from delivery by authorized personnel from a secured delivery area. (3-28-23)

408. DESTRUCTION OR RETURN OF DRUGS OR DEVICES: RESTRICTIONS.

A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise a dispensed drug or prescription device may only be accepted for return as follows: (3-28-23)

01. Potential Harm. When the pharmacist determines that harm could result if the drug is not returned. (3-28-23)

02. Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a seventy-two (72) hour supply for a drug order. (3-28-23)

03. Donation. Those that qualify for return under the provisions of the Idaho Legend Drug Donation Act as specified in Section 54-1762, Idaho Code. (3-28-23)

409. -- 499. (RESERVED)

SUBCHAPTER F – REPORTING REQUIREMENTS AND DRUG OUTLET RECORDKEEPING (Rules 500 through 599)

500. RECORDKEEPING: MAINTENANCE AND INVENTORY REQUIREMENTS.

01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (3-28-23)

02. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained in accordance with federal law: (3-28-23)

03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. (3-28-23)

04. Rebuttal Presumption of Violation. Evidence of an amount of a controlled substance that differs from the amount reflected on a record or inventory required by state or federal law creates a rebuttable presumption that the registrant has failed to keep records or maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law. (3-28-23)

05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law that include at least: (3-28-23)

a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (3-28-23)

b. The identity and quantity of the drugs received and distributed or disposed of; (3-28-23)

c. The dates of receipt and distribution or other disposition of the drugs; and (3-28-23)

d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (3-28-23)

06. Central Records Storage. Records may be retained at a central location in compliance with federal law. (3-28-23)

07. Electronic Records Storage. Records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. (3-28-23)

501. REPORTING REQUIREMENTS.

01. Theft or Loss of Controlled Substances. A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law. (3-28-23)

02. Individual and Outlet Information Changes. Changes in employment or changes to information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change. (3-28-23)

03. Drug Distributor Monthly Reports. An authorized distributor must report specified data on drugs distributed at least monthly to the Board in a form and manner prescribed by the Board. (3-28-23)

502. -- 599. (RESERVED)

SUBCHAPTER G – PRESCRIPTION DRUG MONITORING PROGRAM REQUIREMENTS

(Rules 600 through 699)

600. CONTROLLED SUBSTANCES: PDMP.
Specified data on controlled substances must be reported by the end of the next business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. (3-28-23)

01. Online Access to PDMP. To obtain online access, a prescriber or pharmacist, or their delegate must complete and submit a registration application and agree to adhere to the access restrictions and limitations established by law. (3-28-23)

02. Use Outside Scope of Practice. Information obtained from the PDMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. A delegate may not access the PDMP outside of their supervisor's scope of professional practice. (3-28-23)

03. Profile Requests. Authorized persons without online access may obtain a profile by completing a Board form and submitting it to the Board office with proof of identification and other credentials necessary to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. (3-28-23)

601. – 699. (RESERVED)

SUBCHAPTER H – RULES GOVERNING DRUG COMPOUNDING

(Rules 700 through 799)

700. COMPOUNDING DRUG PREPARATIONS.
Any compounding that is not permitted herein is considered manufacturing. (3-28-23)

01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into

Idaho, except these rules do not apply to: (3-28-23)

a. Compound positron emission tomography drugs; (3-28-23)

b. Radiopharmaceutics; (3-28-23)

c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; (3-28-23)

d. The addition of a flavoring agent to a drug product; and (3-28-23)

e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. (3-28-23)

02. General Compounding Standards. (3-28-23)

a. Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. (3-28-23)

b. Certificate of Analysis (COA). Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a COA must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is necessary on the COA: product name, lot number, expiration date, and assay. (3-28-23)

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (3-28-23)

d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction. (3-28-23)

03. Prohibited Compounding. Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited. (3-28-23)

04. Limited Compounding. (3-28-23)

a. Triad Relationship. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order. (3-28-23)

b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if: (3-28-23)

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (3-28-23)

ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (3-28-23)

c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product. (3-28-23)

05. Drug Compounding Controls. (3-28-23)

a. Policies and Procedures. In consideration of the applicable provisions of USP Chapter 795 concerning pharmacy compounding of non-sterile preparations, USP Chapter 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: (3-28-23)

i. Appropriate packaging, handling, transport, and storage requirements; (3-28-23)

ii. Accuracy and precision of calculations, measurements, and weighing; (3-28-23)

iii. Determining ingredient identity, quality, and purity; (3-28-23)

iv. Labeling accuracy and completeness; (3-28-23)

v. Beyond use dating; (3-28-23)

vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (3-28-23)

vii. Maintaining environmental quality control; and (3-28-23)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (3-28-23)

b. Accuracy. Components including, but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate. The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label. (3-28-23)

c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: (3-28-23)

i. Production date; (3-28-23)

ii. Beyond use date; (3-28-23)

iii. List and quantity of each ingredient; (3-28-23)

iv. Internal control or serial number; and (3-28-23)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (3-28-23)

701. STERILE PREPARATION.

01. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Preparations, these rules apply to all persons, including any business entity, engaged in the practice of sterile compounding and sterile prepackaging in or into Idaho. (3-28-23)

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02. Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug preparation must be sterilized when prepared in the following dosage forms: (3-28-23)

a. Aqueous bronchial and nasal inhalations, except sprays and irrigations intended to treat nasal mucosa only; (3-28-23)

b. Baths and soaks for live organs and tissues; (3-28-23)

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (3-28-23)

d. Irrigations for wounds and body cavities; (3-28-23)

e. Ophthalmic drops and ointments; and (3-28-23)

f. Tissue implants. (3-28-23)

03. Compounder Responsibilities. Compounders and sterile prepackagers are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter; (3-28-23)

a. Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows; (3-28-23)

i. Opened or entered single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile preparations are to be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; (3-28-23)

ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (3-28-23)

iii. Opened single-dose ampules may not be stored for any time period; and (3-28-23)

iv. Multiple-dose containers that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer; (3-28-23)

b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial endotoxins; (3-28-23)

c. No food, drinks, or materials exposed in patient care and treatment areas may enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile preparations are prepared. (3-28-23)

04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile preparations in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. (3-28-23)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated. (3-28-23)

b. Filters must be inspected and replaced in accordance with the manufacturer's recommendations. (3-28-23)

05. Sterile Preparation Equipment. A drug outlet in which sterile preparations are prepared must be

equipped with at least the following: (3-28-23)

a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless written documentation can be provided from the aseptic isolator manufacturer that any component of garbing is not necessary; (3-28-23)

b. A sink; (3-28-23)

c. A refrigerator for proper storage of additives and finished sterile preparations prior to delivery when necessary; and (3-28-23)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet, or a comparable compounding area when authorized by USP Chapter 797. (3-28-23)

06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile preparations are prepared: (3-28-23)

a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (3-28-23)

b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (3-28-23)

c. Audits appropriate for the risk of contamination for the particular sterile preparation including: (3-28-23)

i. Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing; (3-28-23)

ii. Periodic hand hygiene and garbing competency; (3-28-23)

iii. Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager; (3-28-23)

iv. Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months. (3-28-23)

v. Gloved fingertip sampling testing at least annually for personnel who compound low- and medium-risk level compounded sterile preparations and every six (6) months for personnel who compound high-risk level compounded sterile preparations. (3-28-23)

vi. Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, etc.) before dispensing or distributing; (3-28-23)

d. Temperature, logged daily; (3-28-23)

e. Beyond use date and accuracy testing, when appropriate; and (3-28-23)

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (3-28-23)

07. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule. (3-28-23)

702. HAZARDOUS DRUGS PREPARATION.

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In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Preparations and Sterile Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: (3-28-23)

01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. (3-28-23)

02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. (3-28-23)

a. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; (3-28-23)

b. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. (3-28-23)

c. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: (3-28-23)

i. The hazardous drugs in use will not volatilize while they are being handled; or (3-28-23)

ii. Written documentation from the manufacturer attesting to the safety of such ventilation. (3-28-23)

03. Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs. (3-28-23)

04. Labeling. Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills. (3-28-23)

05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. (3-28-23)

06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit-of-use packaging. (3-28-23)

07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste. (3-28-23)

08. Training. Ensure that personnel working with hazardous drugs are trained in hygiene, garbing, receipt, storage, handling, transporting, compounding, spill control, clean up, disposal, dispensing, medical surveillance, and environmental quality and control. (3-28-23)

09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule. (3-28-23)

703. 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. (3-28-23)

02. Adverse Event Reports. Outsourcing facilities must submit to the Board a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with Section 310.305 of Title 21 of the Code of Federal Regulations. (3-28-23)

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