IDAPA 27 – BOARD OF PHARMACY

27.01.03 – RULES GOVERNING PHARMACY PRACTICE

DOCKET NO. 27-0103-1801

NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING
Wednesday, October 24, 2018 – 1:00 p.m. (MDT)

Idaho State Capitol Building
Room WW53
700 W. Jefferson Street
Boise, ID 83702

Written comments received by October 15, 2018, will be included in the Board's distributed meeting materials for consideration. Written comments received between October 15, 2018, and October 24, 2018, will be printed and distributed to Board members at the meeting. For those planning to attend the open, public meeting, written and verbal comments will be accepted by and/or presented before the Board.

The hearing site will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

With the proposed repeal of IDAPA 27.01.06, "Rules Governing Durable Medical Equipment (DME), Manufacturing, and Distribution," updates are needed in this chapter to retain critical rules from that chapter. This docket also makes changes in accordance with House Bills 339 and 351, which passed the 2018 Idaho Legislature unanimously. Lastly, this docket makes several technical corrections and other changes to better align with federal law and existing practice.

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

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 as a result of this rulemaking: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018 Idaho Administrative Bulletin, **Vol. 18-7, pages 158-159**.

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

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Alex Adams, Executive Director, at (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 24, 2018 as described above.

Dated this 30th day of August 2018.

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Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0103-1801
(Only Those Sections With Amendments Are Shown.)

~~***200. PIC: RESPONSIBILITIES AND LIMITATIONS.***~~

~~***01. Drug Outlets that Must Designate a PIC**. The following drug outlets must have a designated PIC by the date of opening and must not thereafter allow a vacancy of a designated PIC to continue for more than thirty (30) sequential days: (7-1-18)*~~

~~***a.** Any drug outlet that dispenses drugs to patients in Idaho; (7-1-18)*~~

~~***b.** Any central drug outlet; and (7-1-18)*~~

~~***c.** Any outsourcing facility. (7-1-18)*~~

~~***02. PIC and Drug Outlet Responsibility**. The PIC is responsible for the management of every part of the drug outlet and its regulated operations. The PIC and the drug outlet each have corresponding and individual responsibility for compliance with applicable state and federal law and these rules. (7-1-18)*~~

~~***03. PIC Oversight Limitations**. A person may neither be designated nor function as the PIC for more than two (2) drug outlets concurrently. (7-1-18)*~~

20~~1~~0. DRUG OUTLETS ~~*THAT DISPENSE PRESCRIPTION DRUGS*~~: MINIMUM FACILITY STANDARDS.
A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: ~~*(7-1-18)*~~( )

01. Security. 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. An alarm or other comparable monitoring system is required for any non-institutional drug outlet that stocks controlled substances and is new or remodeled after July 1, 2018. (7-1-18)

02. Patient Privacy. All protected health information must be stored and maintained in accordance with HIPAA. In addition, a community pharmacy that is new or remodeled after March 21, 2012 must provide and maintain a patient consultation area that affords the patient auditory and visual privacy and is compliant with the Americans with Disabilities Act. (7-1-18)

03. Equipment and Storage. A drug outlet must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity. ~~*(7-1-18)*~~( )

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. (7-1-18)

05. Controlled Substances Storage. ~~*Controlled substances*~~ Drug outlets that dispense prescription drugs must ~~*be*~~ store~~*d*~~ controlled substances in a securely locked, substantially constructed cabinet or safe. However, a pharmacy may disperse substances listed in Schedules II, III, IV and V, in whole or in part, throughout the stock of non-controlled substances if doing so would be likely to obstruct the theft or diversion of the controlled substances. ~~*(7-1-18)*~~( )

06. Controlled Substances Disposal. Expired, excess or unwanted controlled substances that are owned by the drug outlet must be properly disposed of through the services of a DEA-registered reverse distributor or by another method permitted by federal law. (7-1-18)

07. Authorized Access to the Restricted Drug Storage Area. ~~*(7-1-18)*~~

~~***a.***~~ Access to the restricted drug storage area ~~*can occur only when a pharmacist or prescriber is on duty.*~~ ~~*(7-1-18)*~~

~~***b.***~~ ~~*Access*~~ must be limited to ~~*pharmacists, technicians and pharmacist interns, or in the case of a prescriber drug outlet, to prescribers and appropriate support*~~ authorized personnel ~~*in accordance with the prescriber's practice act. A pharmacist or prescriber may, however, authorize an individual temporary access to the restricted drug storage area to perform a legitimate non-pharmacy function if the individual remains under the direct supervision of the pharmacist or prescriber*~~. ~~*(7-1-18)*~~( )

~~***c.***~~ ~~*An institutional facility may also develop an emergency drug access protocol in which a non-pharmacist health professional may enter into the restricted drug storage area of an institutional facility that is otherwise closed, and pursuant to a valid prescription drug order, remove a sufficient quantity of non-controlled drugs necessary to meet the immediate needs of a patient.*~~ ~~*(7-1-18)*~~

20~~2~~1. 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: (7-1-18)

01. Valid Prescription Drug Order. Prescription drugs must only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter D of these rules. (7-1-18)

02. Prospective Drug Review. Prospective drug review, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. (7-1-18)

03. Labeling. Each drug must bear a complete and accurate label as set forth in Subchapter D of these rules. (7-1-18)

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. (7-1-18)

05. Patient Counseling. Counseling, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. (7-1-18)

20~~3~~2. OFFSITE PHARMACY SERVICES.
A drug outlet may provide offsite pharmacy services at one (1) or more locations. When the services being performed are related to prescription fulfillment or processing, the drug outlet must comply with the following: (7-1-18)

01. Policies and Procedures. The originating drug outlet must have written policies and procedures outlining the offsite pharmacy services to be provided by the central drug outlet, or the offsite pharmacist or technician, and the responsibilities and accountabilities of each party. (7-1-18)

02. Secure Electronic File. The parties share a secure common electronic file or utilize other secure technology, including a private, encrypted connection that allows access by the central drug outlet or offsite pharmacist or technician to information necessary to perform offsite pharmacy services. (7-1-18)

03. Exemption. A single prescription drug order may be shared by an originating drug outlet and a central drug outlet, or offsite pharmacist or technician. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section will not be construed as the filling of a transferred prescription or as a wholesale distribution. (7-1-18)

20~~4~~3. DRUG OUTLETS THAT DISPENSE DRUGS TO PATIENTS WITHOUT AN ONSITE PHARMACIST OR PRESCRIBER.
In addition to all other preceding rules of this subchapter, 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: (7-1-18)

01. Security and Access. (7-1-18)

a. The drug outlet must maintain video surveillance with an adequate number of views of the full facility and retain a high quality recording for a minimum of ninety (90) days. (7-1-18)

b. Proper identification controls of individuals accessing the restricted drug storage area must be utilized and access must be limited, authorized, and regularly monitored. (7-1-18)

02. Staffing Limitations. The ratio of pharmacists to support personnel may not exceed one (1) pharmacist for every six (6) technicians and pharmacist interns in total across all practice sites. (7-1-18)

03. Technology. The video and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. (7-1-18)

04. Controlled Substances Inventories. (7-1-18)

a. A perpetual inventory must be kept for all Schedule II controlled substances; and (7-1-18)

b. If a perpetual inventory is not kept for all Schedule III through V substances, the pharmacist or prescriber must inventory and audit at least three (3) random controlled substances quarterly. (7-1-18)

05. Self-Inspection. A pharmacist or prescriber must complete and retain a monthly in-person self-inspection of the drug outlet using a form designated by the Board. (7-1-18)

06. Emergency Situations. (7-1-18)

a. A pharmacist or prescriber must be capable of being on site at the drug outlet within twelve (12) hours if an emergency arises. (7-1-18)

b. 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. (7-1-18)

07. 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. (7-1-18)

08. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act

are exempt from this rule. (7-1-18)

20~~5~~4. 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: (7-1-18)

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. (7-1-18)

02. Policies and Procedures. The supervising drug outlet must develop and implement policies and procedures regarding authorized access to drugs stored in the alternative designated area, documentation of drugs used, drug returns and wastage, and regular inventory procedures. (7-1-18)

03. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. (7-1-18)

04. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. (7-1-18)

05. 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. (7-1-18)

20~~6~~5. – 299. (RESERVED)

SUBCHAPTER D – FILLING AND DISPENSING PRESCRIPTION DRUGS
(Rules 300 through 399 - Filling and Dispensing Prescription Drugs)

300. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. (7-1-18)

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued: (7-1-18)

a. In good faith; (7-1-18)

b. For a legitimate medical purpose; (7-1-18)

c. By a licensed prescriber; (7-1-18)

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; (7-1-18)

e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; or (7-1-18)

f. In the form and including the elements specified in this Subchapter D. (7-1-18)

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. (7-1-18)

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. (7-1-18)

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (7-1-18)

~~*05. Family Members. A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession.* (7-1-18)~~

0~~6~~5. **Expiration**. A prescription drug order is invalid after its expiration date as follows: (7-1-18)

a. A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than ninety (90) days after its date of issue. (7-1-18)

b. A prescription drug order for a controlled substance listed in Schedules III, IV or V must not be filled or refilled more than six (6) months after its date of issue. (7-1-18)

~~*c. A prescription drug order for a non-controlled drug must not be filled or refilled more than fifteen (15) months after its date of issue, unless if extended in accordance with these rules.* (7-1-18)~~

0~~7~~6. ~~*Prescriber Change of Status*~~ **Digital Image Prescriptions**. ~~*A prescription drug order is invalid after ninety (90) days from the date the pharmacist learns of a change in status that precludes a continued prescriber-patient relationship*~~ 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. ~~(7-1-18)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

302. 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, must include at least the following: (7-1-18)

01. Patient's Name. The patient's or authorized entity's name and: (7-1-18)

a. If for a controlled substance, the patient's full name and address; and (7-1-18)

b. If for an animal, the species. (7-1-18)

02. Date. The date issued. (7-1-18)

03. Drug Information. The drug name, strength, quantity and, if for a controlled substance, the dosage form. (7-1-18)

04. Directions. The directions for use. (7-1-18)

05. Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (7-1-18)

06. Signature. ~~*If paper, the pre-printed, stamped or hand printed name and written*~~ A signature sufficient to evidence a valid prescription of either the prescriber or, if ~~*statutorily allowed,*~~ a renewal of a previous prescription, the prescriber's agent~~*'s signature and, if electronic*~~, when authorized by the prescriber~~*'s electronic signature*~~. ~~(7-1-18)~~( )

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. (7-1-18)

08. Exemptions for Non-Controlled Substances. A prescriber may omit the required drug information and directions if the prescriber makes a clear indication that the pharmacist is to finalize the patient's drug therapy plan. ( )

303. 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. (7-1-18)

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. (7-1-18)

03. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal law and only as specifically authorized by the prescriber, except ~~*as follows:*~~ ~~*(7-1-18)*~~

~~***a.*** *A pharmacist acting in good faith and exercising reasonable care may dispense or refill a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills.* *(7-1-18)*~~

~~***b.***~~ that ~~*A*~~a pharmacist may refill a prescription for a non-controlled drug one (1) time in a six (6)-month period when the prescriber is not available for authorization. In such cases, a pharmacist may dispense a refill up to the quantity on the most recent fill or a thirty (30)-day supply, whichever is less. ~~*(7-1-18)*~~( )

304. FILLING PRESCRIPTION DRUG ORDERS: ADAPTATION.
Upon patient consent, a pharmacist acting in good faith and exercising reasonable care may adapt drugs as specified in this rule, provided that the drug is not for a controlled substance, compounded drug, or biological product, and provided that the prescriber has not indicated by any means necessary that adaptation is not permitted. (7-1-18)

01. Change Quantity. A pharmacist may change the quantity of medication prescribed if: (7-1-18)

a. The prescribed quantity or package size is not commercially available; ~~*or*~~ ~~*(7-1-18)*~~( )

b. The change in quantity is related to a change in dosage form~~.~~; ~~*(7-1-18)*~~( )

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

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

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. (7-1-18)

03. Complete Missing Information. A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change. (7-1-18)

~~***04. Medication Synchronization****. A pharmacist may extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.* *(7-1-18)*~~

0~~5~~4. **Documentation**. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record. (7-1-18)

305. FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION.
Drug product substitutions are allowed only as follows: (7-1-18)

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (7-1-18)

02. ~~*Skilled Nursing*~~ Institutional Facility. At the direction of the quality assessment and assurance committee of an ~~*skilled nursing*~~ institutional facility; ~~*(7-1-18)*~~( )

03. Drug Shortage. Upon a drug shortage, a pharmacist may exercise professional judgment, without contacting the prescriber, and may substitute an alternative dose of a prescribed drug, so long as the prescriber's directions are also modified, to equate to an equivalent amount of drug dispensed as prescribed; or (7-1-18)

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (7-1-18)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (7-1-18)

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and (7-1-18)

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (7-1-18)

05. Prescriber-Authorized Substitution. A prescriber may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class provided the following conditions are met: ( )

a. The prescriber has clearly indicated that substitution is permissible by indicating "therapeutic substitution allowed" or a similar designation; ( )

b. The substitution is intended to ensure formulary compliance with the patient's health insurance plan, or, in the case of a patient without insurance, to lower the cost to the patient while maintaining safety; ( )

c. The patient opts-in to the substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution; and ( )

d. If a substitution is made: ( )

i. The prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as is prescribed; and ( )

ii. The pharmacist notifies the patient's original prescriber of the substitution within five (5) business days of dispensing the prescription. ( )

e. Prescriber-authorized substitution does not apply to biological products or narrow therapeutic index drugs. ( )

(BREAK IN CONTINUITY OF SECTIONS)

313. PRESCRIPTION DELIVERY: RESTRICTIONS.

01. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions *to the following* in accordance with federal law, as long as appropriate measures are taken to ensure product integrity: and safety. *(7-1-18)*( )

a. To the patient or the patient's residence, the institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed; (7-1-18)

b. To the patient's licensed or registered healthcare provider, as follows: (7-1-18)

i. If the drug is not a controlled substance; or (7-1-18)

ii. If the drug is a controlled substance that is intended for direct administration by the prescriber or

~~*prescriber's delegate.*~~ ~~*(7-1-18)*~~

~~***c.*** *To another licensed drug outlet.*~~ ~~*(7-1-18)*~~

02. Pick-up or Return by Authorized Personnel. Filled prescriptions may be picked up for or returned from delivery by authorized personnel when the drug outlet is closed for business if the prescriptions are placed in a secured delivery area outside of the restricted drug storage area that is equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion ~~*under policies and procedures developed by the PIC*~~. ~~*(7-1-18)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

SUBCHAPTER E – DRUG OUTLET RECORDKEEPING AND REPORTING REQUIREMENTS
(Rules 400 through 499 - Drug Outlet Recordkeeping and Reporting Requirements)

400. 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. (7-1-18)

02. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained as follows: (7-1-18)

a. Schedule II Prescriptions. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file. (7-1-18)

b. Schedule III through V Prescriptions. Paper prescription drug orders for Schedules III, IV and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV and V controlled substances only or in a readily retrievable manner from other prescription records as required by federal law. (7-1-18)

c. Electronic Prescriptions. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location. The electronic application must be capable of printing or otherwise converting the records into a readily understandable format at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filled. (7-1-18)

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 inventory must be conducted as follows: (7-1-18)

a. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually 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. A separate controlled substances inventory must be taken and retained at each DEA-registered location. (7-1-18)

~~***b.*** *Inventory on PIC Change. A complete controlled substance inventory must be conducted by the incoming PIC or his delegate on or by the first day of employment of the incoming PIC.* ~~*(7-1-18)*~~

~~***c***~~**b.** Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an

inventory of the substance on hand, and thereafter, include the substance in each inventory. (7-1-18)

~~d~~**c.** Drugs Stored Outside a Drug Outlet. In addition to the annual inventory requirements, 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. (7-1-18)

~~e~~**d.** Closing of Pharmacy. A closing inventory must be conducted and retained. (7-1-18)

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. (7-1-18)

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. The records must include at least: ( )

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; ( )

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

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

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

0~~5~~**6. Central Records Storage**. Records may be retained at a central location in compliance with federal law. (7-1-18)

0~~6~~**7. Electronic Records Storage**. Any record required to be kept under this section 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. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

402. REPORTING REQUIREMENTS.

~~***01. PIC Change**. Both an outgoing and incoming PIC must report to the Board a change in a PIC designation within ten (10) days of the change.* *(7-1-18)*~~

0~~1~~**1. 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. (7-1-18)

0~~2~~**2. Individual 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. (7-1-18)

0~~3~~**3. Reporting Adulteration or Misappropriation**. A licensee or registrant must report to the Board any adulteration or misappropriation of a controlled drug in accordance with Section 37-117A. Idaho Code. (7-1-18)

04. 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. ( )