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NOTICE OF RULE MAKING HEARING

Pursuant to Colorado Revised Statutes, Title 12, Article 22 and Title 24, Article 4, CRS (2010), you are hereby advised that the Colorado State Pharmacy Board will hold a public rule making hearing on Thursday, April 21, 2011, at 9:30 a.m., at 1560 Broadway, Conference Room 110 D, Denver, Colorado 80202, for consideration of the following:

Hearing Regarding Repeal, Modification, Amendment, Revision or Adoption of portions of:

Rule	**1.00.00**	**(3 CCR, 719-1)**
Rule	**2.00.00**	**(3 CCR, 719-1)**
Rule	**3.00.00**	**(3 CCR, 719-1)**
Rule	**5.00.00**	**(3 CCR, 719-1)**
Rule	**11.00.00**	**(3 CCR, 719-1)**
Rule	**15.00.00**	**(3 CCR, 719-1)**

The proposed rules under consideration are attached to this notice and fully incorporated herein.

The Board encourages interested parties to submit written comments to the letterhead address regarding any of the above-listed rulemaking matters no later than **March 31, 2011**. In addition, at the time and place designated in this notice, the Board of Pharmacy will afford interested parties an opportunity to submit written information, data, views or arguments. The Board also will afford interested parties an opportunity to make brief oral presentations unless the Board in its discretion determines that such oral presentations are unnecessary. All submissions will be considered. The rules under consideration may be changed or modified after public comment and hearing.

BY ORDER OF THE COLORADO STATE BOARD OF PHARMACY

Wendy Anderson

Wendy Anderson, Program Director

Dated this 4th day of March, 2011.

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, April 21, 2011

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 1.00.18 is to delete redundant language concerning a pharmacist's responsibility for decisions concerning "patient counseling" as it is defined in CRS section 12-22-102(23.5).

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, and 24-4-103.

1.00.18 Patient Counseling.

a. When the patient seeks advice, or when, in the pharmacist's professional judgment, the best interest of the patient will be served, the pharmacist shall offer to advise the patient regarding the prescription.

b. ~~A employer, employer's agent, employee, pharmacist or prescription drug outlet shall not interfere with the professional judgment of the pharmacist to advise the patient regarding a prescription.~~

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, April 21, 2011

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 2.01.50(b) is to remove redundant language. The requirement being deleted is also listed under rule 2.01.53(a)(11). The amendments to 2.01.50(c)(2), 2.01.50(c)(3), 2.01.50(e), 2.01.52(b)(1), 2.01.52(b)(2), and 2.01.53(a)(7) are to detail that when prescriptions are electronically transferred between pharmacies only one pharmacist needs to be involved and modernize old language as far as how the identification of the pharmacist(s) involved in prescription transfers may be documented.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, and 24-4-103.

2.01.50 Transfer of Prescription Orders Between Prescription Drug Outlets.

a. A prescription label or a written copy of a prescription order from another pharmacy may be used for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist who receives such a label or prescription order copy shall either contact the prescribing practitioner for authorization to dispense the prescription, or, alternatively, shall comply with 2.01.52 through 2.01.59.

b. A pharmacist may orally transfer prescription order information for non-controlled substances for the purpose of dispensing a prescription if the information is communicated by one pharmacist to another pharmacist or an intern, or by an intern under the direct supervision of a pharmacist to another pharmacist. ~~The~~

~~transferring prescription drug outlet must communicate the serial number assigned to the prescription order and the receiving prescription drug outlet must record that serial number.~~

c. A prescription drug outlet may transfer a prescription order electronically to another prescription drug outlet for the purpose of dispensing a prescription order.

(1) If the prescription order information is transmitted by facsimile, the transferring pharmacist shall comply with Regulation 2.01.52.

(2) Prescription order information may be transmitted electronically between two compatible computer systems that are capable of complying with the requirements of regulations 2.01.52 and 2.01.53 (1)-(10). In the case of electronic transfers, the transferring and receiving pharmacist are the same person.

(3) In the case of prescription drug outlets that access and share the same data storage device and that can electronically retrieve all ~~that~~ necessary information, if the original prescription order information is not invalidated, each dispensing prescription drug outlet shall be capable of accessing a transaction record that indicates the following information: (a) date, (b) time, and (c) location from which the prescription was dispensed. If the prescription order is assigned a new prescription number at the receiving pharmacy, the prescription information at the originating pharmacy shall be invalidated.

d. The one-time transfer of original prescription information for a controlled substance listed in schedules III, IV, or V for the purpose of dispensing is permissible between pharmacies. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. If the prescription order is assigned a new prescription number at the receiving pharmacy, the prescription may be transferred on a one-time basis only.

e. A pharmacist may authorize an unlicensed assistant to electronically transfer an order, for the purpose of redispensing said order, provided that the ~~ETO~~ electronic transfer is between two compatible computer systems and no changes are made. The pharmacist shall be identified on the transfer record as required by 2.01.52 and 2.01.53.

2.01.52 The transferring pharmacist shall:

a. Write the word "void" across the face of the original prescription order to make the order invalid;

b. Record on the reverse side of the invalidated prescription order:

(1) His/her name~~;~~, license number, initials, or secure electronic identifier;

(2) The name, license number, initials, or secure electronic identifier of the receiving pharmacist or intern;

(3) The name of the receiving prescription drug outlet;

(4) The address and telephone number of the receiving prescription drug outlet; and

(5) The date of the transfer.

(6) In the case of a controlled substance in schedule III through V, the Drug Enforcement Administration registration number of the receiving prescription drug outlet.

c. A pharmacy utilizing a computer for storage and retrieval of information regarding prescription transactions shall be exempt from the requirements of paragraphs (a) and (b) of this regulation if the computer is capable of invalidating the prescription order and retaining as part of the permanent record the information specified in paragraph (b) of this regulation.

2.01.53 The pharmacist receiving the transferred prescription order information shall:

a. Reduce the transferred information to writing or print; write or print the word "transfer" on the face of the transferred prescription order; and provide all information required by law or regulation to be on the prescription order, including:

(1) The date of issue of the original prescription order;

(2) The date of initial compounding and dispensing of the original prescription order;

(3) The number of refills authorized and the original quantity prescribed or any limitations placed on the prescription;

(4) The number of valid refills remaining;

(5) The date of the last refill of the original prescription order;

(6) The prescription order number from which the prescription order information was transferred;

(7) The name, license number, initials, or secure electronic identifier of the transferring pharmacist or intern;

(8) The name of the transferring prescription drug outlet;

(9) The address and telephone number of the transferring prescription drug outlet;

(10) In the case of a controlled substance in schedules III through V, the DEA number of the transferring prescription drug outlet, and the practitioner's DEA number.

~~(11) The pharmacist receiving the prescription transfer shall inform the transferring pharmacist of 2.01.52 and shall request the transferring pharmacist to comply with 2.01.52.~~

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, April 21, 2011

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 3.00.50(e) clarifies that the pharmacist making the initial interpretation and final evaluation of an original prescription or LTCF chart order is identified on a uniformly maintained and readily retrievable document.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, 12-22-130(1)(b) and 24-4-103.

3.00.50 Initial Interpretation and Final Evaluation.

a. Initial interpretation means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/manual transcription and for drug regimen review.

b. Final evaluation means the review of the final prescription to ensure that the ordered medication is properly prepared and placed in a suitable container with appropriate labeling. The pharmacist(s) conducting the final evaluation shall be held accountable for assuring that the identity of the drug that appears on the prescription label corresponds with identity of drug contained therein. When refills are dispensed, the pharmacist conducting the final evaluation shall be held accountable for the appropriate dispensing of refills including all drug utilization reviews as they pertain to refill dispensing.

c. Drug regimen review includes but is not limited to the evaluation of order(s) and patient records(s) for:

1) Known allergies;

2) Rational therapy and contraindications;

3) Reasonable dose, duration of use, and route of administration considering age, gender, and other patient factors;

4) Reasonable directions for use;

5) **Potential or actual adverse drug reactions;**

6) **Drug-drug interactions;**

7) **Drug-food interactions;**

8) **Drug-disease contraindications;**

9) **Therapeutic duplication;**

10) **Proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and**

11) **Abuse/misuse.**

d. **A pharmacist shall conduct an initial interpretation of each new order and a pharmacist shall conduct the final evaluation of each order dispensed. When refills are dispensed, the pharmacist making the final evaluation shall be held accountable for the appropriate dispensing of refills. The pharmacist manager shall be held accountable for the maintenance of all appropriate records.**

e. ~~The original prescription or LTCF order shall bear the identity of the pharmacist making the initial interpretation, by either license number, initials, name or secure electronic identifier.~~ **The pharmacist making the initial interpretation** and final evaluation on prescription or LTCF chart orders **shall be identified by either license number, initials, name, or secure electronic identifier on a uniformly maintained, readily retrievable document.** ~~The order or a~~ The **uniformly maintained, readily retrievable document shall bear the license number, initials, name, or secure electronic identifier of any additional pharmacists involved in the dispensing of the order. The pharmacist conducting the initial interpretation and final evaluation may be the same person.**

f. **In the case where the computer software utilized is not password protected, the initial interpretation and final evaluation shall be maintained in a handwritten format bearing the license number, initials, or name of the responsible pharmacist. In addition, the identification of any other pharmacists involved in the dispensing shall be maintained in the same handwritten format.**

3.00.51 Records of Initial Interpretation and Final Evaluation.

a. Records detailing both the initial interpretation and final evaluation shall be retained at the prescription drug outlet for each prescription dispensed and for at least two years from the date of any transaction pertaining to the order. These records shall include at least the following:

1, The license number, initials, name, or secure electronic identifier of the pharmacist conducting the initial interpretation for each new order;

2. The license number, initials, name, or secure electronic identifier of the pharmacist conducting the final evaluation for each new and refill prescription; and

3. The specific date on which each initial interpretation and final evaluation occurred. In the event the initial interpretation and final evaluation for a new order are conducted on separate dates, both dates shall be recorded to state specifically when both occurred.

b. Each outlet shall maintain, in written format, a notice detailing how initial interpretations and final evaluations are documented in the outlet. Such notice shall include and comply with the following:

1. The manner in which initial interpretations are recorded and maintained in the outlet for all new orders.

2. The manner in which final evaluations are recorded in the outlet for all new and refill prescriptions.

3. A statement that all pharmacy personnel involved in the dispensing of prescriptions have the ability to print, upon request, a record detailing the initial interpretation for each new prescription dispensed and final evaluation for each new and refill prescription dispensed.

4. Such written notice shall be signed and dated by the pharmacist manager. In the event the pharmacist manager changes, the incoming pharmacist manager shall review, sign and date the notice within 72 hours of assuming the duties of pharmacist manager. In the event there is a lapse between the time one pharmacist manager ceases the duty and another assumes the duty, the previous method of recording initial interpretations and final evaluations shall remain in effect.

5. If there are any changes to the outlet's method of documenting initial interpretations and final evaluations, a new written notice detailing the requirements of sections 1., 2., 3. And 4 above shall be executed. This notice shall detail the effective date of change.

6. The outlet shall post these notices on a wall directly next to

the outlet's most current board registration.

7. These notices shall be retained at the outlet for a period of three years from the date last utilized.

8. In the event such notices are not posted, the pharmacist manager shall be held accountable for the failure to post the required notice and any dispensing errors. In the event such notices are not posted during the period of time between one pharmacist manager leaving the position and another assuming the position, the outlet shall be held accountable for the failure to post the required notice and any dispensing errors.

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 5.00.50(b) clarifies that if a non-resident prescription drug outlet ("non-resident pharmacy") relocates to another state, its Colorado non-resident registration can no longer exist because the Colorado registration was predicated upon licensure or registration in the pharmacy's state of residence. Such non-resident pharmacy can apply for another registration utilizing its registration with the state into which it has relocated and become a resident.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, 12-22-130(1)(b) and 24-4-103.

5.00.50 Relocation.

a. In the event of a relocation of an in-state or non-resident prescription drug outlet, the outlet shall submit an application provided by the board along with the prescribed fee at least 30 days prior to the effective date of relocation.

b. The registration of a non-resident prescription drug outlet shall become void and shall be cancelled if the non-resident prescription drug outlet relocates to a state other than that which appears on its registration. In the event the non-resident prescription drug outlet wishes to continue shipping prescriptions into Colorado, it must apply for and receive a new Colorado registration.

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 5.00.60(b) clarifies that if a any in-state or nonresident prescription drug outlet discontinues the practice of pharmacy, it is the responsibility of the pharmacist manager to inform the Board of that action within the noted time frame.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, 12-22-130(1)(b) and 24-4-103.

5.00.60 Discontinuance.

a. Discontinuance shall mean the permanent cessation of the practice of pharmacy in any in state or non-resident prescription drug outlet. For in-state prescription drug outlets, discontinuance shall also be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in 5.01.40(a).

b. Upon the discontinuance of the practice of pharmacy in any in-state or nonresident prescription drug outlet, it shall be the responsibility of the last pharmacist manager of record to remove the prescriptions and/or chart orders to another prescription drug outlet where patrons and/or practitioners are afforded reasonable access to a pharmacist's interpretation of such orders. Such relocation of records shall be made within 72 hours after discontinuance of the practice of pharmacy occurs. THE PHARMACIST MANAGER SHALL SUBMIT A NOTICE, ON A FORM AND MANNER APPROVED BY THE BOARD, DETAILING THE CLOSURE OF THE PRESCRIPTION DRUG OUTLET OR NONRESIDENT PRESCRIPTION DRUG OUTLET WITHIN 72 HOURS AFTER DISCONTINUANCE OF THE PRACTICE OF PHARMACY OCCURS. If the last pharmacist manager of record fails to relocate the records as required herein, the board may direct the removal of the records to a suitable location. The last pharmacist manager of record shall make a reasonable effort to inform patrons of the prescription drug outlet of the location of the records.

c. The Board on request shall provide the owner of any prescription drug outlet an instruction sheet applicable to the transaction prior to discontinuing business, or conducting bankruptcy proceedings, or transferring or selling the prescription drug inventory.

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: Rule 5.01.31 (a) currently requires each pharmacy's principal compounding / dispensing area where drugs are stored to be of continuous square footage. To be deemed continuous, no door can be used to separate various parts of a principal compounding / dispensing area. The purpose of the additions to Rule 5.01.31

(a) is to allow pharmacies, under certain conditions, the ability to use doors that would separate various parts of the principal compounding / dispensing area where drugs are stored.

Statement of Authority: **The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, 12-22-120(2) and (3), and 24-4-103.**

5.01.31 Within every prescription drug outlet as defined in CRS 12-22-102(30.2), there shall be one area designated as the principal compounding/dispensing area. In addition to the principal compounding/dispensing area there may be one or more satellite compounding/dispensing areas ("satellites") which are located in the same building as the principal compounding/dispensing area. The principal compounding/dispensing area and any satellite shall comply with the following conditions:

a. The principal compounding/dispensing area shall not be less than 225 continuous square feet, except that prescription drug outlets registered by the Board prior to the effective date of this regulation that do not meet this space requirement are hereby exempted from such requirement. However, any new prescription drug outlet shall comply with this requirement prior to the granting of the initial registration. Any existing prescription drug outlet which is being remodeled or is being moved from one location to another, whether or not there is a change of address, shall submit documentation required by the Board prior to remodeling or relocation. Satellite compounding/dispensing areas at the same location must not be less than 100 continuous square feet and must be approved by the Board prior to use for compounding/dispensing.

(1) ANY ROOM OR ROOMS INCLUDED WITHIN OR ADJACENT TO THE PRINCIPAL COMPOUNDING / DISPENSING AREA THAT ARE SEPARATED FROM THE PRINCIPAL COMPOUNDING / DISPENSING AREA BY A DOOR MUST MEET THE FOLLOWING:

(A) THE PRESCRIPTION DRUG OUTLET SHALL SUBMIT DOCUMENTATION REQUIRED BY THE BOARD TO REMODEL THE PRINCIPAL COMPOUNDING / DISPENSING AREA PRIOR TO UTILIZING THE ROOM OR ROOMS FOR THE PURPOSES OF COMPOUNDING AND DISPENSING OR FOR THE STORAGE OF PRESCRIPTION DRUG AND CONTROLLED SUBSTANCE STOCKS;

(B) THE DOOR MUST HAVE A CONSPICUOUSLY DISPLAYED SIGN ATTACHED TO IT, AND FACING THE PRINCIPAL COMPOUNDING / DISPENSING AREA, THAT STATES "THIS ROOM IS PART OF THE BOARD-APPROVED DESIGNATED PRINCIPAL COMPOUNDING / DISPENSING AREA";

(C) UNLESS THE DOOR IS USED TO SECURE A ROOM DEDICATED TO STORING CONTROLLED SUBSTANCES, IT SHALL NOT HAVE THE ABILITY TO BE LOCKED OR OTHERWISE SECURED. THE BOARD OR ITS REPRESENTATIVES SHALL HAVE READILY AVAILABLE AND UNIMPEDED ACCESS TO THIS ROOM AT ALL TIMES DURING NORMAL BUSINESS HOURS; AND

(D) IF A LOCKED OR OTHERWISE SECURED DOOR IS USED TO SECURE A ROOM DEDICATED TO STORING CONTROLLED

SUBSTANCES, IT SHALL BE UNLOCKED IMMEDIATELY UPON THE REQUEST OF THE BOARD OR ITS REPRESENATIVES.

b. All compounding/dispensing areas shall be well-lighted and well-ventilated with clean and sanitary surroundings devoted primarily to compounding/dispensing. These areas shall provide necessary protection for drugs, chemicals and devices from deterioration due to light, heat or evaporation and shall be arranged to protect all prescription drugs and devices from pilferage or other unauthorized removal. No areas shall be subject to any condition likely to lead to errors.

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, April 21, 2011

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 11.04.10 is to clarify that prescriptions orders, as retained in the files of prescription drug outlets, must be legible and easily readable.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, and 24-4-103.

11.04.10 A hard copy of every prescription order shall be readily retrievable, ~~and~~legible, and available for inspection for a period of two years from the date of any transaction relating to such prescription order unless the prescription drug outlet has received written Board approval to not retain the original prescription order for non-controlled drugs and Schedule III, IV, and V Controlled Substances. Prescription orders will be deemed to be readily retrievable, ~~and~~legible and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to 2.01.10, and are easily readable without the aid of any special device.. In addition to being filed in numerical sequence, three different prescription files shall be maintained: one file shall consist only of schedule II controlled substance prescription orders; the second file shall consist only of schedule III, IV and V controlled substance prescription orders; and the third file shall consist of all non-controlled substance prescription orders. Filing of prescription orders in any manner other than by numerical sequence will result in such prescription orders being deemed not readily retrievable and available.

A hard copy of every chart order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order. The LTCF chart orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing. Chart orders for schedule III, IV, and V controlled substances shall be readily identifiable from non-controlled chart orders. Schedule II orders shall be retained separately from all other orders.

If a prescription drug outlet utilizes both prescription orders and chart orders, assigning serial numbers to both with the same computer system, the orders must be filed sequentially by serial number.

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, April 21, 2011

Proposed Changes with Statement of Basis, Purpose, and Authority

Basis and Purpose: The purpose of the amendment to Rule 15.01.11(a)(9) clarifies that wholesalers that exclusively distribute veterinary prescription drugs need to have a designated representative. That designated representative need not comply with the requirements detailed for wholesalers that do not distribute veterinary prescription drugs exclusively. The addition of rule 15.01.11(d) clarifies that if an out-of-state wholesale relocates to another state, its Colorado registration can no longer exist because the Colorado registration was predicated upon licensure or registration in the wholesaler's state of residence. Such out-of-state wholesaler can apply for another registration utilizing its license or registration with the state into which it has relocated and become a resident. Out-of-State wholesalers may be registered with the Board utilizing, among other components, either an inspection report from the resident state's pharmacy board or that completed by a Board-approved accreditation body. The addition of 15.01.11(e) clarifies that if the wholesaler's registration was obtained utilizing a Board-approved accreditation body inspection report, the registration of the out-of-state wholesalers becomes void should the accreditation from the Board-approved accreditation body be withdrawn or revoked. The addition of 15.09.11(e) provides that wholesalers that distribute animal drugs exclusively are exempt from the requirements of pedigrees.

Statement of Authority: The Board is granted authority to promulgate these rules pursuant to CRS sections 12-22-108, 12-22-110, 12-22-801(3)(b), 12-22-805(7), and 24-4-103.

15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(1) The name, full business address, and telephone number of the applicant;

(2) All trade or business names used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution or prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, sole proprietorship, limited liability company, or government entity); and

(5) The name(s) of the owner and operator of the applicant including:

(a) If a person, the name of the person;

(b) If a partnership, the name of each partner, the name of the partnership, and the federal employer identification number (FEIN);

(c) If a corporation, the name and title of each corporate officer and director, the name of the parent company, the corporate names, the federal employer identification number of the business, and the name of the state of incorporation; and

(d) Name of the business entity. If a sole proprietorship, the full name of the sole proprietor, and the name and federal employer identification number of the business entity.

(e) If a government entity, identify the name of director and the name of the governmental agency he/she represents.

(6) If a limited liability company, the name and title of each member, federal employer identification number (FEIN) of the business, and name of parent company, if any.

(7) A list of the licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803.

(9) ~~Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8.~~Wholesalers that distribute animal drugs exclusively must have a designated representative. However, the requirements of 15.01.11(a)(8)(g-i)) are not required.

b. Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

c. Any registered wholesale drug distributor that is accredited by a board approved accreditation body shall inform the board, in writing, within 72 hours if its accreditation is:

(1) Expired;

(2) Suspended;

(3) Revoked; or

(4) Withdrawn.

d. An out-of-state wholesaler's Colorado registration shall be deemed void and shall be cancelled if the wholesaler relocates to a state other than that which is listed on its Colorado registration. In the event the wholesaler wishes to continue distributing prescription drugs into and within Colorado, it must apply for and receive a new Colorado registration indicating its current state of residence.

e. A wholesaler's Colorado registration shall be deemed void and shall be cancelled if it was registered in Colorado using an inspection from a board-approved accreditation body and the accreditation issued by that accreditation body is revoked or withdrawn.

15.09.00 Recordkeeping.

15.09.10 All records of receipt, distribution or other disposal of prescription drugs and/or controlled substances shall be available to the Board on request for inspection, copying, verifying or other proper use. If authorization has been granted to maintain certain records centrally at another location, these records shall be made available within two business days (48 hours maximum.) Records kept at an inspection site or other site than can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. If recap records are available, the Board may, at its option, utilize them, but the original records must also be produced if requested and shall be considered the document of record in any case.

15.09.11 Records in general. All wholesalers registered by the Board shall maintain such records and inventories of prescription drugs as may be required by these regulations or any other state or federal law or regulation pertaining to such drugs. Such records shall be maintained on a current basis and shall be complete and accurate for all drugs which the outlet manufactures, receives, distributes or otherwise disposes of in any other manner. Records, including pedigrees, and inventories of controlled substances shall be deemed to be "complete" only if each individual record and inventory contains all required information regarding each specific transaction, and if the set of records and inventories contains all information and documents required to be kept by state and federal laws, rules, and regulations. A record or inventory shall be deemed to be "accurate" only if it is a complete, true and factual statement regarding or reflecting each specific transaction. A set of records or inventories shall be deemed to be "accurate" only if they are complete, and when considered as a whole, they demonstrate that the controlled substances and/or the records and inventories pertaining thereto have been handled in compliance with all applicable laws or regulations and that all such controlled substances are properly accounted for.

a. All such records, including pedigrees, shall be retained for a period of at least three years after the date of any transaction relating to such record or inventory by any process providing an exact duplicate of the original order in a reproducible quality acceptable to the Board. Records shall be retained in a format that cannot be altered.

b. A wholesaler in the possession of a pedigree (a document or electronic file containing information that records each distribution of any given prescription drug that leaves the normal distribution channel) for a prescription drug shall verify that each transaction on the pedigree has occurred prior to distributing the prescription drug.

c. The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or first authorized distributor of record through the acquisition and sale by a wholesaler until final sale to a pharmacy or other person dispensing or administering the prescription drug. When a wholesaler distributes a product to another wholesaler, both the distributing and receiving wholesaler shall maintain a copy of the pedigree. The pedigree shall include at least the following:

(1) The name, address, telephone number, and, if available, the e-mail address of each owner of the prescription drug and each wholesaler of the drug;

(2) The name and address of each location from which the prescription drug was shipped, if different from that of the owner;

(3) The transaction dates;

(4) Certification that each recipient has authenticated the pedigree;

(5) The name of the prescription drug;

(6) The dosage form and strength of the prescription drug;

(7) The size and number of containers;

(8) The lot number of the prescription drug; and

(9) The name of the manufacturer of the finished dosage form.

d. Effective January 1, 2017, all wholesalers shall be required to use electronic pedigrees.

e. Wholesalers that distribute animal drugs exclusively are exempt from the requirements of pedigrees.

Records on an automated data processing system or subsequent storage of such records must be immediately retrievable (via monitor display or hard copy printout).