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. The amendments to 2.01.50(c), 2.01.50(e), 2.01.52(b)(1), 2.01.52(b)(2), and 2.01.52(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 ~~re~~dispensing 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) 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, January 20, 2011

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.

COLORADO STATE BOARD OF PHARMACY

Rulemaking Hearing, January 20, 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, January 20, 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 wholesalers cannot relocate to another state other than that which they were originally registered in without obtaining a new registration. 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. A wholesaler's registration shall be deemed void and shall be cancelled if the wholesaler relocates to a state other than that which is listed on its registration. In the event the wholesaler wishes to continue distributing prescription drugs into and within Colorado, it must apply for and receive a new registration.

e. A wholesaler's registrations 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).

15.09.12 Retrievability of records. For the purposes of these regulations, records and inventories shall be deemed "readily retrievable" if they meet the following requirements:

a. The following records shall be maintained on the premises of the registrant at all times and shall be made available for inspection by the Board or its inspectors immediately upon request:

(1) All DEA-222 forms executed during the three years preceding the request;

(2) All inventories of controlled substances required to be taken during the three years preceding the request;

(3) All records of receipt (invoices for drugs received and credited) of controlled substances, distribution, loss, surrender or disposal in manner of prescription drugs and controlled substances during the three years preceding the request;

(4) List(s) of symbols and codes, if applicable. Symbols and codes may be used to identify any manufacturer, distributor, or repackager. If such symbols and codes appear in the records of the registrant, the registrant shall keep a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable and available for examination by the Board for at least three years.

b. The following records shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors:

(1) All unexecuted DEA-222 forms.

(2) Specific records requested by the inspector if the inspector determines the records are not maintained in a readily retrievable manner.

(3) Records of receipt of non-controlled prescription drugs.

c. Pedigrees shall be made available to the board or its inspectors within five business days of request.

15.09.13 Inventories of controlled substances. Any inventory of controlled substances shall comply with the following:

a. Each inventory shall contain a complete and accurate record of all controlled substances (including outdated controlled substances, returns from customers, and items ordered but not yet invoiced) on hand on the date the inventory is taken. The inventory shall be maintained in written, typewritten or printed form at the outlet. Schedule II drugs shall be separated from schedule III, IV, and V drugs. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant.

b. The inventory shall be taken either as of opening of business or as of the close of business on the inventory date and it shall be recorded on the inventory. In the event the prescription drug outlet is open 24 hours per day, the inventory shall specify the time the inventory was conducted.

c. After the initial inventory is taken, the outlet shall take new inventory of all stocks of controlled substances on hand at least every two years.

d. On the effective date of a law or rule on which a previously non-scheduled drug is added to any schedule of controlled substances, every prescription drug outlet that possesses that drug shall take an inventory of all stocks of the drug on hand. Thereafter, that drug shall be included in each inventory made by the outlet.

e. The following information shall be recorded on the inventory:

(1) The name of the drug;

(2) Each finished form of the drug (strength and dosage form);

(3) The number of units or volume of each finished form; and

(4) The number of commercial containers of each finished form.

g. All controlled substance inventories shall be retained at the prescription drug outlet for at least three years from the date of such inventory.

15.09.14 Receipts.

a. In-state prescription drug wholesalers shall only receive prescription drugs and controlled substances from an entity that is registered by the Colorado State Board of Pharmacy. This section shall not apply to intracompany or reverse distribution transactions.

15.09.15 Records of receipt of prescription drugs and controlled substances shall contain the following information for each such substance received:

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received if a controlled substance;

f. Name of the labeler of the drug if it is labeled only with its generic name;

g. Name of the receiver;

h. Address of the receiver;

i. Name of the distributor that physically distributed the drug directly to the receiver;

j. Address of the distributor where the drug was directly distributed from;

k. DEA registration number of the distributor if a controlled substance;

l. DEA registration number of the receiver if a controlled substance;

m. The DEA form 222 or an electronic order form shall be completed for each schedule ii controlled substance received.

15.09.16 All records of receipt (including credit invoices) of prescription drugs and controlled substances shall be maintained for a period of time not less than two years from the date the drugs were received. Records of receipt (including credit invoices) of non-controlled prescription drugs need not be maintained on the premises provided that they shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors.

15.09.17 All records of receipt of schedule II controlled substances shall be maintained separately from all other records.

15.09.18 Records of receipt of schedule III, IV, and V controlled substances may be maintained with other records of receipt. However, the record shall be readily identifiable from the records of receipt of non-controlled drugs.

15.09.19 Distribution.

a. A manufacturer or wholesaler as defined in regulation 15.01.00 shall furnish prescription drugs only to a person or entity licensed by the appropriate regulatory board. Before furnishing prescription drugs to a person not known to the wholesaler, the wholesaler shall affirmatively verify that the person or entity is legally authorized to receive the prescription drugs by contacting the appropriate regulatory board.

b. Prescription drugs furnished by a manufacturer or wholesaler shall be delivered only to a practitioner authorized by law to prescribe the drug or to an entity licensed or registered by the Board. In the case of such entities registered or licensed by the Board, drugs shall be distributed only to the registered or licensed address. The manufacturer or wholesaler may furnish prescription drugs to an authorized person or agent of the person listed on the license if the identity and authorization of the recipient is properly established and the method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person or agent.

c. Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving agent signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

15.09.20 Records of distribution of controlled substances and prescription drugs. An outlet which distributes prescription drugs and/or controlled substances shall record the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

e. The name of the manufacturer or the NDC number of the drug if labeled only with its generic name;

f. The date of distribution;

g. If just an NDC number is used the wholesaler or manufacturer shall maintain a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable for examination by the Board for at least ~~two~~ THREE years;

h. The name and address of the distributing wholesaler;

i. The name and address of the receiver;

j. If a controlled substance is distributed, the record shall also indicate the drug enforcement registration number of the distributing outlet and the receiver; and

k. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form or an electronic order.

15.09.21 These records of distribution shall be retained for a period of time not less than two years from the date of the distribution.

15.09.22 Records of distribution may be maintained electronically if the following requirements are met:

a. The wholesaler must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.

b. Have and maintain a complete on-line distribution file that is printable on the inspector's request, or

c. Have a "lock-out" feature that prevents editing of distribution information.

d. The Board or its inspectors must be able to inspect and review the distribution transactions of the wholesaler. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:

(1) Print a report of all distribution transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to; date of distribution, drug name, strength and dosage form, and registrants receiving the distribution;

or

(2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1)

(3) It is the responsibility of the manager to ensure that all wholesale staff is aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the outlet manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these regulations.

e. If the outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:

(1) The name of the drug;

(2) The strength of the drug;

(3) The dosage form if appropriate;

(4) The quantity of the drug;

(5) The manufacturer name and/or NDC number of the drug if labeled only with its generic name;

(6) The date of distribution;

(7) The name and address of the distributing outlet;

(8) The name and address of the receiver; and

(9) When a controlled substance is distributed, the record shall also indicate the drug enforcement registration number of the distributing outlet and the receiver.