

Tracked changes were deleted or accepted and did not appear in the statutory language of the recommendations as intended.

Differences between original and republished version are in **bold**.

Beginning on page 33 through page 60.

Recommendation 6 - Combine all statutory violations under the heading of “unprofessional conduct” and separate the listing of violations from the Board action that is authorized. Amend section 12-22-125, C.R.S., and enact section 12-22-125.2, C.R.S., to read as follows:

12-22-125. Licenses or registrations may be denied, suspended, or revoked. UNPROFESSIONAL CONDUCT – GROUNDS FOR DISCIPLINE.

(1) The board may deny, suspend, or revoke any license to practice as a pharmacist or pharmacy intern, after a hearing held in accordance with the provisions of this section, upon proof that the licensee. THE TERM “UNPROFESSIONAL CONDUCT” AS USED IN THIS ARTICLE, MEANS A LICENSEE OR REGISTRANT, WHERE APPLICABLE, **WHO:**

(a) Is guilty of misrepresentation, fraud, or deceit in procuring or attempting to procure **OR RENEW** a license or registration;

(b) Is guilty of the commission of a felony or has had accepted by a court a plea of guilty or nolo contendere to a felony **OR HAS RECEIVED A DEFERRED SENTENCE FOR A FELONY. IN CONSIDERING THE CONVICTION OF A CRIME, THE BOARD SHALL BE GOVERNED BY THE PROVISIONS OF SECTION 24-5-101, C.R.S.**

(c) Has violated any of the provisions of this part 1, the lawful rules and regulations of the board, or any state or federal law pertaining to drugs **OR ANY ACTS AS SET FORTH IN SECTION 12-22-126, C.R.S.**

~~(2)(a)(I)(d)~~ Is unfit or incompetent by reason of negligence, habits, or physical or mental illness, or for any other cause, to practice as such;

~~(2)(a)(II)(e)~~ **Is habitually intemperate or is addicted to or uses to excess habit-forming drugs or controlled substances, as defined in section 12-22-303 (7);** IS ADDICTED TO, DEPENDENT ON, OR ENGAGES IN THE HABITUAL USE OR ABUSE OF INTOXICATING LIQUORS, A HABIT-FORMING DRUG, OR A CONTROLLED SUBSTANCE AS DEFINED IN SECTION 18-18-102(5), C.R.S.

~~(2)(a)(III)(f)~~ Knowingly permits a person not licensed as a pharmacist or pharmacy intern to engage in the practice of pharmacy;

~~(2)(a)(IV)(g)~~ Has had his or her license to practice pharmacy in another state revoked or suspended **OR OTHERWISE DISCIPLINED for disciplinary reasons** or has committed acts in any other state that would subject him or her to disciplinary action in this state;

~~(2)(a)(V)(h)~~ Has engaged in advertising which is misleading, deceptive, or false;

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- (i) HAS DISPENSED A SCHEDULE III, IV, OR V CONTROLLED SUBSTANCE ORDER MORE THAN SIX MONTHS AFTER THE DATE OF ISSUE OF THE ORDER;
 - (j) HAS ENGAGED IN THE PRACTICE OF PHARMACY WHILE ON INACTIVE STATUS;
 - (k) HAS FAILED TO MEET GENERALLY ACCEPTED STANDARDS OF PHARMACY PRACTICE;
 - (l) FAILS OR HAS FAILED TO PERMIT THE BOARD OR ITS AGENTS TO CONDUCT A LAWFUL INSPECTION;
 - (m) HAS VIOLATED ANY LAWFUL BOARD ORDER;
 - (n) HAS COMMITTED ANY FRAUDULENT INSURANCE ACT AS DEFINED IN SECTION 10-1-127, C.R.S.;
 - (o) HAS WILLFULLY DECEIVED OR ATTEMPTED TO DECEIVE THE BOARD OR ITS AGENTS WITH REGARD TO ANY MATTER UNDER INVESTIGATION BY THE BOARD;
 - (p) HAS FAILED TO NOTIFY THE BOARD OF ANY CRIMINAL CONVICTION OR DEFERRED JUDGMENT WITHIN 30 DAYS OF SUCH CONVICTION OR JUDGMENT;
 - (q) HAS FAILED TO NOTIFY THE BOARD OF ANY DISCIPLINE AGAINST HIS LICENSE IN ANOTHER STATE WITHIN 30 DAYS OF SUCH DISCIPLINE;
 - ~~(2)(a) The board may deny, suspend, or revoke any license to practice as a pharmacist or pharmacy intern, after a hearing held in accordance with the provisions of this section, upon proof that the licensee. (MOVED FROM BEFORE 12-22-125(1)(a))~~
 - (2)(b) In considering the conviction of a crime, the board shall be governed by the provisions of section 24-5-101, C.R.S.
- 12-22-125.2 DISCIPLINARY ACTION. (1) THE BOARD MAY DISCIPLINE LICENSEES OR REGISTRANTS WHEN IT DETERMINES THAT SUCH LICENSEE OR REGISTRANT HAS ENGAGED IN UNPROFESSIONAL CONDUCT.
- {previously 12-22-125(3)}(a) THE BOARD SHALL DENY A LICENSE IN ACCORDANCE WITH SECTION 24-4-104, C.R.S. Proceedings for the **denial**, suspension, or revocation of a license or registration and judicial review shall be in accordance with the provisions of article 4 of title 24, C.R.S., and the hearing and opportunity for review shall be conducted pursuant to said article by the board or an administrative law judge at the board's discretion.
- {previously 12-22-125(4)}(b) Upon the finding of the existence of grounds for discipline of any person holding or seeking a license or registration or the renewal thereof under the provisions of SECTION 12-22-125, C.R.S., **this part 1**, the board may impose one or more of the following penalties:
- (a)(l) Suspension of the offender's license or registration for a period to be determined by the board;

~~(b)~~(II) Revocation of the offender's license or registration;

~~(c)~~(III) Restriction of the offender's license or registration to prohibit the offender from performing certain acts or from practicing pharmacy in a particular manner for a period to be determined by the board;

~~(d)~~(IV) Refusal to renew the offender's license or registration;

~~(e)~~(V) Placement of the OFFENDER **accused** on probation and supervision by the board for a period to be determined by the board;

~~(f)~~(VI) Suspension of the registration of the outlet owned by the offender or in which the offender is employed for a period to be determined by the board.

{previously 12-22-125(5)(a)}~~(2)~~ The board may also include in any disciplinary order that allows the licensee or registrant to continue to practice such conditions as the board may deem appropriate to assure that the licensee is physically, mentally, morally, and otherwise qualified to practice pharmacy in accordance with the generally accepted professional standards of practice, including any or all of the following:

~~(I)~~(a) Submission by the respondent to such examinations as the board may order to determine the respondent's physical or mental condition or professional qualifications;

~~(II)~~(b) The taking by the respondent of such therapy courses of training or education as may be needed to correct deficiencies found either in the hearing or by such examinations;

~~(III)~~(c) The review or supervision of the respondent's practice as may be necessary to determine the quality of his or her practice and to correct deficiencies therein; and

~~(IV)~~(d) The imposition of restrictions upon the nature of the respondent's practice to assure that he or she does not practice beyond the limits of his or her capabilities.

{previously 12-22-125(5)(a)(IV)(b)}~~(3)~~ Upon failure of the licensee or registrant to comply with any conditions imposed by the board pursuant to paragraph ~~(1)(b)(7), (a) of this subsection (5)~~, unless due to conditions beyond the licensee's or registrant's control, the board may order suspension of the offender's license or registration in this state until such time as the licensee or registrant complies with such conditions.

~~(4)~~ IN ADDITION TO ANY OTHER PENALTY WHICH MAY BE IMPOSED PURSUANT TO THIS SECTION, ANY REGISTRANT VIOLATING ANY PROVISION OF THIS ARTICLE OR ANY RULES OR REGULATIONS PROMULGATED PURSUANT TO THIS ARTICLE MAY BE FINED NOT LESS THAN FIVE HUNDRED DOLLARS NOR MORE THAN FIVE THOUSAND DOLLARS FOR EACH SUCH VIOLATION.

{previously 12-22-125(6)(a)}~~(5)~~(a) When a complaint or an investigation discloses an instance of misconduct which, in the opinion of the board, does not warrant formal action by the board but which should not be dismissed as being without merit, a letter of admonition may be sent by certified mail to the pharmacist against whom a complaint was made and a copy thereof to the person making the complaint.

{previously 12-22-125(6)(b)} (b) When a letter of admonition is sent by certified mail by the board to a pharmacist complained against, such pharmacist shall be advised that he or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt~~ of the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

(c) If the request is timely made, the letter of admonition shall be deemed vacated, and the matter shall be processed by means of formal disciplinary proceedings.

{previously 12-22-125(7)}(6) When a complaint or an investigation discloses an instance of conduct that does not warrant formal action by the board but the board determines that continuation of such conduct could warrant action if continued, a confidential letter of concern may be sent by certified mail to the pharmacist against whom the complaint was made or who was the subject of investigation. If a complaint precipitated the investigation, a response shall be sent to the person making the complaint.

The Board's disciplinary powers and the grounds for discipline are currently scattered throughout various places in the statute. Grounds for discipline can be found in sections 12-22-125, C.R.S., 12-22-126, C.R.S., 18-18-304, C.R.S., and 18-18-414, C.R.S. This makes enforcement of Board actions difficult and haphazard at best. There are potential legal challenges that could be made to Board actions pursuant to some of these sections. In order to organize and clarify what is prohibited, it is recommended that all administrative infractions be in one place in the Act. This would grant the Assistant Attorney General to the Board the ability to charge all infractions administratively whether or not the District Attorney decided to charge some of the infractions criminally. Other Boards in the Department of Regulatory Agencies have consolidated infractions under the heading of "unprofessional conduct."

The revised section 12-22-125, C.R.S., contains all administrative infractions for which the Board could discipline. Some of these are broad and would take the interpretation of the Board. Most of the items listed were already in statute in one of the locations cited above. A few of the items are new, based upon lists of infractions used by other professional licensing boards in the Division of Registrations.

Proposed section 12-22-125.2, C.R.S., Disciplinary Action, addresses the Board's power to take various types of actions against licensees and registrants when they violate the unprofessional conduct section 12-22-125, C.R.S. These two sections separate the listing of the infractions from the Board action that is authorized when such infractions occur.

Recommendation 7 - Change the timelines for appealing a letter of admonition to 30 days from the date of mailing, rather than 20 days from the date of proven receipt. Amend section 12-22-125(6)(b) C.R.S., which is being renumbered as 12-22-125.2(5)(a), C.R.S., to read as follows:

When a letter of admonition is sent by certified mail by the board to a pharmacist complained against, such pharmacist shall be advised that he or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt~~ of the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

In practice, the current statutory provision requires a letter of admonition to be mailed via certified mail, return receipt requested. This is the only verifiable way to prove the date on which such letter is received.

However, it is not uncommon for letters of admonition to be returned to the Board as undeliverable or unclaimed. One reason is that pharmacists relocate and do not always notify the Board of their new addresses as required. An additional consideration here is that State mail is not forwarded, it is returned to the Board as undeliverable.

A more pessimistic explanation is that the pharmacist simply refuses to sign for the letter, thus preventing the tolling period from beginning.

The Colorado Court of Appeals recently addressed this issue in *Colorado State Board of Medical Examiners v. Roberts*, 42 P.3d 70 (Colo. App. 2001). In *Roberts*, the court reviewed a provision in the Medical Practice Act that is substantially similar to the statute under discussion here. The Board of Medical Examiners issued a letter of admonition to Dr. Roberts and mailed it to him at his place of business via certified mail, return receipt requested. However, Dr. Roberts and his staff refused to sign for the letter on two separate occasions. Three months later, Dr. Roberts requested that the Board of Medical Examiners vacate the letter of admonition and institute formal disciplinary proceedings against him. The Board of Medical Examiners refused, stating that two notices of attempted delivery by the U.S. Postal Service was sufficient to constitute receipt and begin the 20-day tolling period for requesting formal disciplinary proceedings.

Dr. Roberts and the Court of Appeals disagreed. In focusing on the plain language of the statute, the court held that “receipt” in the statute requires actual receipt.

Since the Act contains language that is substantially similar to the statutory provision reviewed in *Roberts*, it is not unreasonable to believe that at some point, the Board could encounter a similar problem.

The recommended language attempts to expedite the disciplinary process while protecting the rights of the pharmacist. By requiring the letter of admonition to be mailed by certified mail, the Board will be able to establish the date on which it is mailed. To allow for delivery time, and to be consistent with other appeals timelines, the time in which a pharmacist may request formal disciplinary proceedings is extended from 20 days to 30 days.

This recommendation neither restricts nor expands the powers of the Board or the rights of the pharmacist. Rather, it attempts to correct a procedural problem that may be exacerbated by the *Roberts* decision.

Recommendation 8 – Conform the definition of “controlled substance” in the Drugs and Druggists Act to the section in the Colorado Criminal Code that defines “controlled substance”. Amend section 12-22-303(7), C.R.S., to read as follows:

12-22-303(7) “Controlled substance” SHALL HAVE THE SAME MEANING AS THAT DEFINED IN SECTION 18-18-102(5), C.R.S. ~~means a drug, substance, or immediate precursor included in schedules I to V of part 2 of article 18 of title 18, C.R.S.~~

Section 12-22-303(7), C.R.S., defines a controlled substance as “a drug, substance, or immediate precursor included in schedules I to IV of Part 2 of Article 18 of Title 18, C.R.S.”

Section 18-18-102(5), C.R.S., a section of the Colorado Criminal Code (Criminal Code) defines a controlled substance in an identical manner except that it goes on to state, “including cocaine, marihuana, and marihuana concentrate.”

Tetrahydrocannabinols, commonly referred to as “THC”, is listed as a Schedule I Controlled Substance at section 18-18-203(2)(c)(XXIII), C.R.S. Section 12-22-303(32)(a), C.R.S., defines “THC” as,

synthetic equivalents or the substances contained in the plant, or in the resinous extractives of, cannabis, sp., or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity . . .

Thus, THC is a part of the marihuana plant, but an individual could potentially test positive for marihuana and not THC, which is the controlled substance under the Act.

In 2001, the Board of Nursing sought to take disciplinary action against a certified nurse aide (CNA) who reported to work in an intoxicated state and tested positive for cocaine, alcohol and marihuana. Because the Nurse Aide Practice Act references the Drugs and Druggists Act, which includes THC as a controlled substance, but not marihuana specifically, the administrative law judge (ALJ) requested the Board of Nursing’s Assistant Attorney General, to establish the relationship between THC and marihuana in order to proceed to hearing whether the marihuana in the CNA’s system was grounds for disciplinary action. This involved research, legal analysis of the relevant statutes, and obtaining an affidavit from a pharmacist.

Since THC is listed as a Schedule I Controlled Substance, and the Criminal Code specifically includes marihuana in its definition of a controlled substance, it is clear that the General Assembly intended that a practitioner who is found to have abused or excessively or habitually used marihuana be subject to disciplinary action. The recommended amendment will more clearly state the General Assembly’s intention.

Two other points are worth noting in relation to this issue. First, most, if not all, of Colorado’s professional practice acts contain language similar to that at issue here – they reference the Drugs and Druggists Act.

Finally, in 2000, the Colorado Constitution was amended to legalize the use of marihuana for people suffering from debilitating medical conditions. Colo.Const. art. XVIII, §14. This recommendation will not infringe upon an individual’s opportunity to exercise the rights granted under this constitutional provision so long as the practitioner does not report to work while under the influence of marihuana, just as a practitioner could receive discipline for reporting to work while under the influence of alcohol. For an individual who as obtained the necessary approvals and permissions to use marihuana for medicinal purposes, a showing of abuse, or habitual or excessive use would be similar to such a showing for alcohol.

*Recommendation 9 - Update the Pharmacy Peer Health Assistance Diversion Program. Amend sections 12-22-601(2), **12-22-603(3)(b)**, and 12-22-606, C.R.S., to read as follows:*

12-22-601(2) It is the intent of the general assembly that the pharmacy peer health assistance diversion program and its related procedures shall be utilized by the state board of pharmacy IN CONJUNCTION WITH OR as an alternative to the use of disciplinary proceedings by the board, which proceedings are by their nature time-consuming and costly to the people of this state. The pharmacy peer health assistance diversion program is hereby established to alleviate the need for such disciplinary proceedings, while at the same time providing safeguards that protect the public health, safety, and welfare. The general assembly further declares that it is its intent that the state board of pharmacy will act to implement the provisions of this article.

The Board should be able to use the Peer Health Assistance Diversion Program not only as an alternative to discipline, but also in conjunction with discipline.

(incorrect cite – moved from within changes to 12-22-606) 12-22-603(3)(b) Effective July 1, 1994, as a condition of licensure and licensure renewal in this state, every applicant shall pay to the administering entity that has been selected by the board pursuant to the provisions of paragraphs (d) and (e) of this subsection (3) an amount set by the board not to exceed twenty-eight dollars ~~biennially~~ PER YEAR, which amount shall be used to support designated providers that have been selected by the board to provide assistance to pharmacists needing help in dealing with physical, emotional, psychiatric, psychological, drug abuse, or alcohol abuse problems which may be detrimental to their ability to practice

In Subsection (3)(b), the money allotted for this program should be increased. Currently, the program has nearly twice as many participants as the dental program, but licensees pay only one-half of what the dentists pay.

12-22-606. Rehabilitation evaluation committee – created. (1) The board shall establish a rehabilitation evaluation committee, which shall consist of five members to be appointed by the board. Each PHARMACIST member of the committee shall serve UP TO A MAXIMUM OF TWO TERMS ~~for a term~~ of four years; MEMBER'S TERMS SHALL BE STAGGERED ~~except that, of the three voting members, one shall serve an initial term of one year, one shall serve an initial term of two years, and one shall serve an initial term of three years. Other than the staff member for the board, no member shall serve more than one full four-year terms.~~ The members shall be selected as follows: Three members who are licensed pharmacists including one who has recovered from an addiction to alcohol or drugs; one member who is the staff member for the board; and one member who is ~~the director of a program provided by a pharmacy peer health assistance organization.~~ A PSYCHIATRIST OR A LICENSED MENTAL HEALTH PROVIDER. The staff member for the board and the peer health assistance program director shall be nonvoting members of the committee.

(2)(a) The committee shall meet as necessary to review applications to participate in the pharmacy peer health assistance diversion program. For each application, the committee shall make a recommendation to the board that the application be approved or that it be rejected. The board shall either grant or deny applications, based upon reasonable grounds which shall be stated in writing. Such applications may also include requests by licensees to continue in practice while participating in an approved program. The committee shall make a

recommendation to the board that such request to continue in practice be approved or rejected. In those cases where a committee has recommended approval of the application for participation in the program, the licensee may begin participation in the program of the designated pharmacy peer health assistance organization pending final board action on the committee's recommendation. If a committee has recommended that a request to continue in practice be approved, such licensee may continue to practice pending final board action on the committee's recommendation.

The terms of the members of the Rehabilitation Evaluation Committee should be extended to two four-year terms, as it requires significant time to educate new persons to participate fully. In addition, it is recommended that a psychiatrist or licensed mental health professional replace the director of the program provided by the pharmacy peer health assistance organization.

Technical Changes to the Pharmacy Law

The current Act has provisions that are ambiguous, unclear and outdated and has been amended several times since its enactment. Technical changes are necessary to improve and update the Act.

In recognition of the many recent changes in the practice of pharmacy, the National Association of Boards of Pharmacy has developed a Model Act for Boards of Pharmacy (Model Act). Though the statute has been amended slightly over the years, it has not kept pace with changes in the practice of pharmacy. The Model Act is designed to address changes in the practice of pharmacy. The public should have the benefit of statutes that are current with professional practices. Many of the recommendations that follow are premised on the Model Act while others are statutory changes to enhance and clarify the responsibility of the Board.

Due to the large number of additions and statutory clean-up recommendations, the following recommendations have been made in the order of the current statute for easier identification.

Recommendation 10 - Amend specific definitions in section 12-22-102, C.R.S., and make conforming amendments throughout the Drugs and Druggists Act to read as follow:

12-22-102(1) ~~"Administration" means the giving of medication to a patient by a pharmacist qualified to administer drugs by authorization of a physician.~~ "ADMINISTER" MEANS THE DIRECT APPLICATION OF A DRUG TO THE BODY OF A PATIENT OR RESEARCH SUBJECT BY INJECTION, INHALATION, INGESTION, OR ANY OTHER MEANS.

Subsection one is deleted and language from the Model Act was inserted. The definition currently in law does not specifically define what is meant by administration. This recommended language adds needed specificity to the definition.

12-22-102(5) "Casual sale" means a ~~sale~~ TRANSFER, DELIVERY OR DISTRIBUTION to a corporation, individual, or other entity, other than a consumer, entitled to possess prescription drugs; except that the amount of drugs TRANSFERRED, DELIVERED OR DISTRIBUTED ~~sold~~ in such manner by any registered prescription drug outlet or hospital other outlet shall not exceed five percent of the total ~~amount of drugs sold annually~~ NUMBER OF DOSAGE UNITS OF DRUGS DISPENSED AND DISTRIBUTED ON AN ANNUAL BASIS by such outlet.

The recommended changes in this section alter the definition of a casual sale to encompass not only sales but also transfers of any nature. As the section now reads, entities would be able to transfer large quantities of drugs without compliance with regulatory standards if no money was exchanged. This is not in the best interest of the public. In general, in order to track the distribution of drugs and the providers that exchange them, normal regulatory constraints should apply. The intent of casual sale is to allow for small transfers without extensive restriction. Once a transfer becomes a certain size it should meet compliance standards. In addition, current statutory language is ambiguous regarding the amounts of drugs that can be transferred in a casual sale. It is difficult for inspectors to clearly advise facilities due to this ambiguity.

12-22-102(6) ~~"Compound" means to mix, weigh, or otherwise prepare ingredients, as specified in the prescription order of a practitioner, in accordance with the statutes and regulations of pharmacy and to insure that a label is prepared in accordance with the prescription order and placed on or securely attached to the container meeting compendia standards.~~ "COMPOUNDING" MEANS THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OF A DRUG OR DEVICE (i) AS THE RESULT OF A PRACTITIONER'S PRESCRIPTION DRUG ORDER OR CHART ORDER OR INITIATIVE BASED ON THE PRACTITIONER / PATIENT / PHARMACIST RELATIONSHIP IN THE COURSE OF PROFESSIONAL PRACTICE, OR (ii) FOR THE PURPOSE OF, OR AS AN INCIDENT TO, RESEARCH, TEACHING, OR CHEMICAL ANALYSIS AND NOT FOR SALE OR DISPENSING. COMPOUNDING ALSO INCLUDES THE PREPARATION OF DRUGS OR DEVICES IN ANTICIPATION OF PRESCRIPTION DRUG ORDERS BASED ON ROUTINE, REGULARLY, OBSERVED PRESCRIBING PATTERNS.

The language defining "compound" should be deleted and more specific language from the Model Act defining "compounding" inserted for further clarification.

12-22-102(7) "Delivery" means the actual, constructive, or attempted transfer OF A DRUG OR DEVICE from one person to another ~~of a drug or device~~, whether or not ~~there is an agency relationship~~ FOR A CONSIDERATION.

The language defining "delivery" should be amended and language from the Model Act inserted for further clarification.

12-22-102(8) "Device" means an instrument, apparatus, ~~machine, contrivance, or implant or a similar or related article other than a drug, including any component part or accessory which is:~~ IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR OTHER SIMILAR OR RELATED ARTICLE, INCLUDING ANY COMPONENT PART OR ACCESSORY, WHICH IS REQUIRED UNDER FEDERAL LAW TO BEAR THE LABEL, "CAUTION: FEDERAL LAW REQUIRES DISPENSING BY OR ON THE ORDER OF A PHYSICIAN."

- ~~(a) Recognized in the official compendia or any supplement thereto;~~
- ~~(b) Intended for use in the diagnosis, treatment, or prevention of disease or other conditions in humans and animals; and~~
- ~~(c) Required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist~~

The language defining "device" should be deleted, and language from the Model Act inserted for further clarification

12-22-102(9) “Dispense” means ~~to prepare a drug or device pursuant to a lawful prescription order of a practitioner, together with an appropriate label, in a suitable container for subsequent administration to or use by a patient or other individual entitled to receive the prescription order.~~ THE INTERPRETATION, EVALUATION, AND IMPLEMENTATION OF A PRESCRIPTION DRUG ORDER OR CHART ORDER, INCLUDING THE PREPARATION OF A DRUG OR DEVICE TO A PATIENT OR PATIENT’S AGENT IN A SUITABLE CONTAINER APPROPRIATELY LABELED FOR SUBSEQUENT ADMINISTRATION TO OR USE BY A PATIENT.

12-22-102(10) "Distribution" means the ~~delivery~~ TRANSFER of a drug or device other than by administering or dispensing.

The language defining “dispense” should be deleted, and language from the Model Act inserted for further clarification.

The use of the word delivery in this section confuses the definition of “distribution,” as the word “delivery” is already specifically defined in statute. Transfer is not currently defined and has a generally accepted meaning.

12-22-102(11.5) “FILL” MEANS TO PREPARE A DRUG OR DEVICE PURSUANT TO A LAWFUL ORDER OF A PRACTITIONER, TOGETHER WITH AN APPROPRIATE LABEL, IN A SUITABLE CONTAINER FOR SUBSEQUENT ADMINISTRATION TO OR USE BY A PATIENT OR OTHER INDIVIDUAL ENTITLED TO RECEIVE THE ORDER.

The word “fill” is used regularly throughout the profession by laypersons and pharmacists. This new definition of “fill” is the same as the current definition of dispense.

~~12-22-102(13) "Habit forming drug" means any drug or medicine which is required under the state food and drug law or the federal "Food, Drug, and Cosmetic Act" to be labeled as a habit forming drug.~~

This language from the federal Food, Drug and Cosmetic Act is antiquated and no longer necessary. The addictive properties of drugs are addressed in the Uniform Controlled Substances Act pursuant to section 18-18-101, et seq, C.R.S.

12-22-102(16.5) "Location" means the physical confines of an individual building ~~or at the same address.~~

Pharmacies are registered according to their locations. As the Act currently exists, a complex could have several phar in several buildings and register only one of those entities as a pharmacy if all the buildings in the complex had the same address. This situation places the public at risk, as the other buildings would not be inspected nor monitored for compliance with pharmacy regulations.

For example, without notifying the Board, a registered outlet (pharmacy) opened a satellite facility in a different building on its campus. During an inspection of the primary facility, the inspector was informed that one of the pharmacists was working in the "satellite" outlet. The registrant had one address but more than one facility on the campus. The registrant operated an outlet for years without the Board knowing of its existence and, consequently, it was never inspected.

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12-22-102(17) "Manufacture" means to cultivate, grow, or prepare by other process drugs for sale to wholesalers or other persons entitled to purchase drugs other than the ultimate user, but "manufacture" does not include the COMPOUNDING AND dispensing of a prescription drug pursuant to a prescription order.

This section is incomplete without the language concerning compounding. The responsibility for compounding lies with the licensed pharmacist, not the manufacturer, and is currently included in the definition of the "practice of pharmacy."

12-22-102(20) "Nonprescription drug" means ~~a medicine or drug which may be sold without a prescription which is prepackaged for use by the consumer, prepared by the manufacturer or producer for use by the consumer, properly labeled and unadulterated in accordance with the requirements of the state food and drug law and the federal "Food, Drug, and Cosmetic Act". The term shall not apply to any drug that is designated under any law or regulation of this state or federal law or regulation as a habit-forming drug or a controlled substance, as defined in section 12-22-303 (7).~~ A DRUG WHICH MAYBE SOLD WITHOUT A PRESCRIPTION AND WHICH IS LABELED FOR USE BY THE CONSUMER IN ACCORDANCE WITH THE REQUIREMENTS OF THE LAWS AND RULES OF THIS STATE AND THE FEDERAL GOVERNMENT.

The Model Act definition of "nonprescription drug" is concise and adds clarity to the current statutory definition. The current definition is so complex that it takes an inordinate amount of time to establish that the definition had been met at an administrative law hearing.

12-22-102(22) "Official compendia" means the official United States Pharmacopeia, NATIONAL FORMULARY, HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES or any supplements thereto.

This recommendation conforms the definition of "official compendia" to the definition of "drug" found in section 12-22-102(11)(a)(I),C.R.S.

12-22-102(22.5) "Order" means:

(a) A prescription order which is any order, other than a chart order, authorizing the dispensing of a single drug or device that is written, mechanically produced, computer generated and signed by the practitioner, transmitted electronically or by facsimile, or by other means of communication by a practitioner TO A LICENSED PHARMACY and which includes the name or identification of the patient, the date, and sufficient information for compounding, dispensing, and labeling; or

The word "single" as used here is not comprehensive, as sometimes physicians write more than one order on each prescription.

12-22-102(23) "OTHER Outlet" means any ~~prescription drug outlet,~~ hospital THAT DOES NOT OPERATE A REGISTERED PHARMACY, ~~institution, nursing home,~~ rural health clinic, ~~convalescent home, extended care facility,~~ family planning clinic, ~~wholesaler, manufacturer, or mail order vendor, other than a pharmacist,~~ SCHOOL, JAIL, COUNTY HEALTH DEPARTMENT, COMMUNITY HEALTH CLINIC, UNIVERSITY AND/OR COLLEGE that has facilities in this state registered pursuant to this article and that engages in the

COMPOUNDING, dispensing, AND delivery, ~~distribution, manufacturing, wholesaling, or sale~~ of drugs or devices.

This section as currently written has caused numerous problems for the Board. The meaning of the word “institutions” has been unclear. The definition encompasses a number of facilities that are not similar, have little in common in the regulatory scheme for pharmacies, and cannot be generalized. This recommendation suggests using the term “other outlets” and redefining it to include only those types of facilities referred to in this Subsection (23). Manufacture is defined in Subsection (17), wholesaler in Subsection (34), and prescription drug outlets are defined in Subsection (30.2). The Board has no jurisdiction over nursing homes; therefore, references to them should be deleted, as should references to similar facilities over which the Board has no jurisdiction. Defining “other outlets” separately would clarify those entities that must meet the regulatory criteria for “other outlets.”

12-22-102(24.2) “PHARMACY TECHNICIAN” MEANS AN UNLICENSED PERSON WHO PERFORMS THOSE FUNCTIONS SET FORTH IN PARAGRAPH (b) OF SUBSECTION (26) OF THIS SECTION UNDER THE SUPERVISION OF A PHARMACIST.

Amend the remainder of Article 22 to conform with this recommendation by deleting all references to “unlicensed assistant” and replacing it with “pharmacy technician.”

Effective July 1, 2002, the term “unlicensed assistant” pursuant to section 12-22-102(33.5), C.R.S., was repealed along with other responsibilities of the pharmacy manager. Previously, section 12-22-102(33.5)(a), C.R.S., stated "Unlicensed assistant means an unlicensed person who performs those functions set forth in paragraph (b) of subsection (26) of this section under the supervision of a pharmacist. A pharmacist manager of a prescription drug outlet employing an unlicensed assistant shall file with the board the name and date of birth of each unlicensed assistant who is employed by the outlet.”

However, the term “unlicensed assistant” still exists in other parts of the statute and should be defined. The term “pharmacy technician” is generally used in this industry and more aptly describes the position of unlicensed assistant.

12-22-102(26) “Practice of pharmacy” means: (a) ~~An initial interpretation, selection of ingredients and final evaluation of each prescription order or chart order, the participation in drug selection and drug utilization reviews, the participation in administration of drugs, the provision of pharmaceutical care including patient counseling and prospective drug review, drug and drug-related research not including prescriptive authority, the advising and providing of information concerning utilization of drugs and devices in the treatment of an injury and the treatment and prevention of disease, and the offering or performing of these health services, operations, or transactions necessary in the conduct, operation, and control of a prescription drug outlet by a pharmacist~~ THE INTERPRETATION, EVALUATION, IMPLEMENTATION AND THE DISPENSING OF ORDERS; PARTICIPATION IN DRUG AND DEVICE SELECTION, DRUG ADMINISTRATION, DRUG REGIMEN REVIEWS, AND DRUG OR DRUG-RELATED RESEARCH; PROVISION OF PATIENT COUNSELING AND THE PROVISION OF THOSE ACTS OR SERVICES NECESSARY TO PROVIDE PHARMACEUTICAL CARE IN ALL AREAS OF PATIENT CARE; AND

(b) ~~The responsibility for the compounding, dispensing, labeling (except nonprescription drugs), delivery, storage, and distribution of drugs and devices and the maintenance of proper records thereof;~~ THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OR DELIVERY OF A DRUG OR DEVICE, PROPER AND SAFE STORAGE OF DRUGS AND DEVICES, AND MAINTENANCE OF PROPER RECORDS FOR THEM.

The language defining “dispense” should be deleted, and language from the Model Act inserted for further clarification.

12-22-102(30) "Prescription drug" means a drug which, prior to being dispensed or delivered, is to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription." or “Rx ONLY” OR "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

“Rx Only” language should be added to comply with federal law.

12-22-102(30.2) "Prescription drug outlet" means any PHARMACY outlet registered pursuant to this article where prescriptions are ~~filled or~~ compounded, and ~~are sold,~~ dispensed, ~~offered, or displayed.~~

The word “pharmacy” should be added to this definition since it is the most generally accepted term used in the profession and by laypersons. There is confusion concerning the use of the term “prescription drug outlet.” The other recommended changes in this subsection are for greater specificity and to delete unnecessary terms.

12-22-102(30.3) "Refill" means the COMPOUNDING AND dispensing of any drug ~~by a practitioner~~ pursuant to a previously executed order.

The amended definition clarifies the process of refilling a prescription.

12-22-102(32.6) "Supervision" means that a licensed pharmacist is on the location and ~~immediately and~~ readily available to consult with and assist unlicensed personnel performing tasks described in subsection (26) (b) of this section.

“Immediately” was deleted because the reality of practice is that the supervising pharmacist is “readily available,” not necessarily immediately, but within a reasonable time.

12-22-102(34) "Wholesaler" means a corporation, individual, or other entity with facilities in this state which buys drugs or devices for resale ~~and OR distribution~~ DISTRIBUTES to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers.

The definition of wholesaler should include any type of transfer of drugs or devices. Therefore, “and” is replaced by “or.”

Recommendation 11 - Amend the powers and duties of the Board for greater clarification. Amend section 12-22-110, C.R.S., to read as follows:

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Several changes are recommended for this section of the Act referencing the powers and duties of the Board. The Board's powers have not been clearly and concisely defined throughout, therefore, the following recommendations add greater clarification to the Act.

12-22-110(1)(e) Administer examinations AND DETERMINE THE QUALIFICATIONS AND FITNESS OF ~~to~~ applicants for licensure;

12-22-110(1)(f) Keep a record of all licenses, ~~and~~ registrations, AND RENEWALS FOR A REASONABLE PERIOD OF TIME, AND ~~of all license and registration renewals~~, A RECORD OF ALL suspensions, ~~and~~ revocations, AND ANY OTHER DISCIPLINE and A RECORD of its own proceedings;

12-22-110(1)(h) MAKE INVESTIGATIONS, HOLD HEARINGS, AND TAKE EVIDENCE IN ALL MATTERS RELATING TO THE EXERCISE AND PERFORMANCE OF THE POWERS AND DUTIES VESTED IN THE BOARD AND, IN CONNECTION WITH ANY INVESTIGATION, SUBPOENA WITNESSES, ADMINISTER OATHS, AND COMPEL THE TESTIMONY OF WITNESSES AND THE PRODUCTION OF BOOKS, PAPERS, AND RECORDS RELEVANT TO ANY SUCH INVESTIGATION OR HEARING. ANY SUBPOENA ISSUED PURSUANT TO THIS ARTICLE SHALL BE ENFORCEABLE BY THE DISTRICT COURT.

The recommended language in sections 12-22-110(1)(e) - (h), C.R.S., is modeled from language existing in other board statutes. Although these powers are probably implied, they are not guaranteed without specific language.

12-22-110(4)(a) Whenever a duly authorized agent of the board finds or has probable cause to believe that in any REGISTERED OUTLET ~~prescription drug outlet~~ any drug, nonprescription drug, or device is adulterated or misbranded within the meaning of the "Colorado Food and Drug Act", part 4 of article 5 of title 25, C.R.S., he shall affix to such article a tag or other appropriate marking giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board, its agent, or the court. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission from the court.

This recommendation expands the Board's embargo power to other facilities beyond prescription drug outlets.

The editor's note that was added to this section relates to the legalities applicable to statutory adoption. This information is unnecessary in this Act.

Recommendation 12 - Allow research companies to be exempt from the Act. Amend section 12-22-116.5, C.R.S., to read as follows:

12-22-116.5. Exemption from licensure - hospital residency programs – home renal dialysis – RESEARCH COMPANIES. (1) The board shall have the authority to approve hospital residency programs in the practice of pharmacy. Persons accepted into an approved hospital residency program who are licensed to practice pharmacy in another state shall be exempt

from the licensing requirements of this part 1 so long as their practice is limited to participation in the residency program.

12-22-116.5(3) A MANUFACTURER WHICH MUST OBTAIN A PRESCRIPTION DRUG OR DEVICE SOLELY FOR USE IN ITS RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WHICH DOES NOT FURTHER DISTRIBUTE THE DRUG OR DEVICE MAY APPLY TO THE BOARD FOR A WAIVER OF REGISTRATION UNDER THIS ARTICLE. THE BOARD MAY GRANT SUCH A WAIVER PROVIDED THAT THE MANUFACTURER SUBMITS TO THE BOARD THE NAME OF THE DRUG OR DEVICE IT REQUIRES AND A SWORN AFFIDAVIT CERTIFYING THAT THE DRUG OR DEVICE WILL ONLY BE USED FOR NECESSARY RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WILL NOT BE FURTHER DISTRIBUTED. THIS WAIVER SHALL NOT APPLY TO ANY CONTROLLED SUBSTANCE AS DEFINED IN STATE OR FEDERAL LAW.

Occasionally a manufacturer needs a prescription drug for internal use in research, development, manufacturing and/or testing of a product. A typical example might be the need for sterile water for cleaning or calibration of equipment. The manufacturer does not qualify for registration in any category listed in section 12-22 120, C.R.S., because it does not produce or sell prescription drugs. Without a registration, wholesale suppliers of prescription drugs are prohibited from distributing to the manufacturer. This recommendation would create an avenue for the Board to grant an exemption for such situation, so the manufacturer would be permitted to obtain the needed product.

Recommendation 13 - Update and revise responsibilities of pharmacy managers of prescription drug outlets. Amend section 12-22-119(1)(b), C.R.S., to read as follows:

12-22-119(1)(b) The registration of any prescription drug outlet shall become void if the pharmacist manager in whose name the prescription drug outlet registration was issued ceases to be engaged as the manager, and the owner shall close the prescription drug outlet unless such owner has employed a pharmacist, and, within FOURTEEN (14) ~~seven~~ days after termination of the former manager's employment, has made application to transfer the registration to the new manager and has paid the transfer fee therefor.

Currently, an owner of a prescription drug outlet has only seven days in which to make an application to transfer the registration to a new manager when the previous one has left that position. This time period is unduly short and an increase to a 14-day period is recommended.

Recommendation 14 - Amend the frequency of registration for outlets. Amend section 12-22-120(1) to read as follows:

12-22-120(1) All outlets with facilities in this state shall register ~~annually~~ with the board in one of the following classifications:

It is an administrative burden for the agency to be required to renew businesses every year. All other licensees and registrants are on a biennial schedule. For administrative efficiency, the agency would like to renew pharmacists one year and businesses the next year.

Recommendation 15 - Clarify language to allow the transfer of facility registrations. Amend section 12-22-120(4), C.R.S., to read as follows:

12-22-120(4) Registrations issued by the board pursuant to this section are ~~not~~ transferable or assignable ONLY PURSUANT TO THIS ARTICLE AND BOARD REGULATIONS.

There are several provisions in the statute that address the transfer of ownership of a pharmacy. The provisions of section 12-22-114(1)(g),(h) & (m), C.R.S., regarding fees for transferring a prescription drug outlet and section 12-22-119(2), C.R.S., regarding application for the transfer of ownership of a prescription drug outlet conflict with the provisions of section 12-22-124, C.R.S. As currently written, this section precludes any transfer of facility registrations. This is not the current practice of the Board or the intent of the Act.

Recommendation 16 - Clarify the authority to transfer products between affiliated other outlets. Amend sections 12-22-121(2), (3) and (5), C.R.S., to read as follows:

12-22-121(2) Except as provided in subsection (7) of this section, a manufacturer of drugs may sell or give any drug to any wholesaler of drugs or to a licensed hospital or registered prescription drug outlet OR OTHER OUTLET, or he may give or sell any drug to any practitioner authorized by law to prescribe the same.

12-22-121(3) A wholesaler may sell or give any drug or device to another wholesaler of drugs or devices, to any licensed hospital or registered prescription drug outlet OR OTHER OUTLET, or to any practitioner authorized by law to prescribe the same.

12-22-121(5)(b) IN THE CASE OF A COUNTY HEALTH DEPARTMENT WHICH OPERATES REGISTERED OTHER OUTLETS, ONE REGISTERED OTHER OUTLET MAY MAKE A CASUAL SALE OF A DRUG TO ANOTHER REGISTERED OUTLET PROVIDED THAT (I) THE DRUG IS SOLD IN THE ORIGINAL SEALED CONTAINER IN WHICH IT WAS ORIGINALLY RECEIVED FROM THE WHOLESALER; (II) NO SUCH CASUAL SALE IS MADE TO ANY REGISTERED OUTLET THAT IS NOT OWNED AND/OR OPERATED BY THAT COUNTY HEALTH DEPARTMENT; AND (III) THE AMOUNT SOLD DOES NOT EXCEED THE FIVE PERCENT LIMIT ESTABLISHED BY SECTION 12-22-102(5), C.R.S.

During an Other Outlet Task Force meeting, it was proposed that such transfers would be helpful when one outlet has an excess of drugs and another outlet needs additional drugs. Rather than wasting the excess drugs, they could be transferred to where they are needed. There is still the five percent limitation on total amount as expressed in section 12-22-102(5), C.R.S., that defines “casual sale.”

Currently, some of the larger county health departments already register as wholesalers if they wish to purchase drugs in bulk and distribute them to their satellite “other outlets.” Re-packaging, however is not allowed, unless they comply with federal regulations. The recommended change is proposed to reduce the red tape involved for government entities when carrying out their public responsibilities.

Subsections (2) and (3) are revised to incorporate “other outlets” into their language.

Recommendation 17 - Clarify the pharmacist’s authority to refill a prescription order. Amend section 12-22-122(2), C.R.S., to read as follows:

12-22-122(2) A pharmacist may refill a prescription order for any prescription drug EXCLUDING CONTROLLED SUBSTANCES without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety, and welfare. Such prescription refill shall only be in an amount sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this subsection (2) continue medication beyond seventy-two hours. However, if the prescriber states on the prescription that there shall be no emergency filling of the prescription, then the pharmacist shall not issue any medication not authorized by the prescription. Neither a prescription drug outlet nor a pharmacist shall incur any liability as a result of refusing to refill a prescription pursuant to this subsection (2).

Subsection (2) needs to be clarified to conform to federal law. The pharmacist's authority to refill a prescription when the prescriber cannot be reached is limited to prescriptions for non-controlled substances only.

Recommendation 18 – Replace the word “pharmacist” with the word “prescription drug.” Amend section 12-22-130(1)(b), C.R.S., to read as follows:

12-22-130(1)(b) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription drug outlet shall maintain at all times a valid, unexpired license, permit, or registration to conduct the ~~pharmacist~~ PRESCRIPTION DRUG outlet in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription drug outlet shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

This recommendation conforms to Recommendation 2 on page 53 that revises the definition of “prescription drug outlet” in section 12-22-102(30.2), C.R.S.