Colorado State Board of Pharmacy
Basis and Purpose and Statement of Authority
Rulemaking Hearing on November 7, 2012

1. **Basis and Purpose for Changing all references in the rules to the "Colorado State Board of Pharmacy", "Colorado Board of Pharmacy', and "Board of Pharmacy" to "Board", for removing all applicable references to "regulation" or replacing all applicable references to "regulation" to "rule", and changing all references to "DEA" to "Drug Enforcement Administration".** The basis and purpose of removing or amending the language is to use consistent terminology throughout all of the Board rules.

   Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

2. **The Basis and Purpose for changing references to "Unlicensed Assistant" to "Pharmacy Technician in rules 1.00.16(b), 2.01.30, 2.01.50(e), and 3.00.70.** "Pharmacy Technician" is defined in 12-42.5-102(30), C.R.S. The change is being made to make the rule language consistent with that of the statute. Prior to "pharmacy technicians" being defined in statute in 2003, they were referred to as "unlicensed assistants" in the rules. This change will modernize the language.

   Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

3. **The Basis and Purpose for the amendment to Rule 2.01.53** is to remove the (a) from the rule because there is no (b).

   Authority for amendment to Rule 2.01.53: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

4. **The Basis and Purpose for the addition of Rule 3.00.75 is** to establish and clarify that placement of a prescription into another outer container and labeling that container with the patient's name or any other identifying information is included in the definition of the "Practice of Pharmacy" under Section 12-42.5-102(31), C.R.S. This issue pertains in many situations of placing a finished prescription in a bag for the patient to pick up. The rule brings this activity within a pharmacist's supervisory limitations as set forth in 12-42.5-119, C.R.S. The intent of the rule change is to reduce the number of prescriptions inadvertently delivered to the wrong patient.

   Authority for Promulgation of Rule 3.00.75: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

5. **The Basis and Purpose for the changes to 3.00.81 (a) through (m), 3.00.83, 3.00.84(b) and (c), and 3.00.88(a)(1)** are to effectuate the legislative policy set forth in Senate Bill 12-161 which amended 12-22-133, C.R.S. (recodified by House Bill 12-1311 to 12-42.5-133, C.R.S.) to allow for the return of unused medications from correctional facilities for reuse.

   Authority for amendments to rules 3.00.81(a) through (m), 3.00.83, 3.00.84 (b) and (c) and 3.00.88(a)(1): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-133(4) and 24-4-103, C.R.S.

6. **The Basis and Purpose for the amendment to Rule 3.00.88(d)** is to change the Rule number which is referenced. It was incorrectly referenced as 3.00.87(b)(1) through (12) and the correct citation is 3.00.88(b)(1) through (12).

   Authority for amendment to rule 3.00.88(d): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-133(4) and 24-4-103, C.R.S.

7. **The Basis and Purpose for the amendments to Rule 3.01.10 is** to specify under what conditions a prescription drug outlet may distribute drugs it packages as provided for in 12-42.5-118(15)(b), C.R.S.

   Authority for amendments to Rule 3.01.10: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-118(15)(b) and 24-4-103, C.R.S.

8. **Basis and Purpose for additions, recodifications, deletions, and amendments to rules 4.00.10 4.00.20, 4.00.30, 4.00.40, 4.01.00 and 4.02.00:** Rule 4.00.10 was deleted and replaced with a definitions section which defines terms used within Rule 4.00.00. A definition of "intern" was added which is consistent with the change to the "intern" definition that occurred during the 2012 Legislative Session under 12-42.5-102(17), C.R.S. Rule 4.00.20 was deleted as 12-22-111, C.R.S. was deleted in the 2012 Legislative Session and not recodified into Title 12, Article 42.5. Consequently, the Board no longer certifies or approves "preceptors." Rule 4.00.20 was replaced with the requirements for obtaining an intern license. Rule 4.01.00 and 4.02.00 were deleted. The requirements delineated in those rules were moved to 4.00.40 and 4.00.30, respectively. The requirements for pharmacist and intern licensing were modernized. In addition, the requirements of 12-42.5-118(13), C.R.S., which allow an intern, as part of the curriculum of a school or college of pharmacy, to obtain intern hours supervised by a registered manufacturer of by another regulated individual as provided for in rules adopted by the Board are effectuated in the "regulated individual" definition and the requirements for pharmacist licensure.

Authority for deletions, recodifications, amendments, and additions to 4.00.10 4.00.20, 4.00.30, 4.00.40, 4.01.00 and 4.02.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-102(17), 12-42.5-111, 12-42.5-112(4), (5), and (8), 12-42.5-114(3), 12-42.5-118(13) and 24-4-103, C.R.S.

9. **The Basis and Purpose for the amendments to Rule 5.00.60** are to change the term "discontinuance" to a more suitable recognizable term for "closure." This rule details the requirements for prescription drug outlets when they cease to operate.

   Authority for amendments to Rule 5.00.60: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

10. **The Basis and Purpose for the amendment to Rule 5.00.70** is to effectuate the legislative changes of 12-42.5-116(1)(b), C.R.S. from the 2012 Legislative Session which allow prescription drug outlets thirty days to make application and pay the required fee too change the pharmacist manager.

    Authority for amendment to Rule 5.00.70: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-116(1)(b), and 24-4-103, C.R.S.

11. **The Basis and Purpose for the deletions, amendments, and additions to Rule 5.01.31** are to add clarifying language, delete duplicative language, and remove many of the requirements for minimum equipment for prescription drug outlets. Pharmacy practice has changed substantially since the addition of the minimum equipment requirements. The requirements are being changed to allow prescription drug outlets to maintain the equipment for the type of business they conduct. It will no longer be prescribed in rule. 5.01.31(k) is being deleted to remove the requirement that pharmacies must provide adequate services, including compounding. This language is no longer relevant in that many pharmacies do not compound and some pharmacies do not dispense prescriptions. The change of name of the Pharmaceuticals and Pharmacists Act in 5.01.31(f)(1) has been changed to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act to reflect the new name of the Act as set forth in Title 12, Article 42.5, C.R.S.

    Authority for deletions, amendments, and additions to Rule 5.01.31: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

12. **The Basis and Purpose for the amendments to Rule 7.00.10** is to change name of the Pharmaceuticals and Pharmacists Act to the Pharmacists, Pharmacy Businesses, and

Pharmaceuticals Act. This reflects the new name of the Act as set forth in Title 12, Article 42.5, C.R.S.

Authority for deletions, amendments, and additions to Rule 7.00.10: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

13. **The Basis and Purpose for the amendments to Rule 7.00.20** is to change the word "discontinuance" to "closure" to be consistent with the amendment to Rule 5.00.60.

    General Authority for amendments to Rule 7.00.20: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

14. **The Basis and Purpose for the amendments to Rule 8.00.10** is to allow flexibility for the labeling of prescriptions dispensed through central prescription processing (where more than one pharmacy participates in the dispensing process) to use either the name and address of the originating pharmacy or the fulfillment pharmacy.

    General Authority for amendments to Rule 8.00.10: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

15. **The Basis and Purpose for the addition of Rules 10.00.05(a) and (b)** are to effectuate the legislative intent of 12-42.5-118(5)(a)(III), C.R.S. which requires the board to define "emergency kit" and "starter dose."

    General Authority for addition of Rules 10.00.05(a) and (b): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-118(5)(a)(III), and 24-4-103, C.R.S.

16. **The Basis and Purpose for the amendment to 12.00.10** is to remove references to 12-22-108, C.R.S.. This law, when recodified to 12-42.5-105 during the 2012 Legislative Session, removed the reference to radiopharmaceuticals.

    Authority to amend Rule 12.00.10: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

17. **The Basis and Purpose for the amendment to 12.00.32(a)** is to update the reference material requirements for prescription drug outlets that specialize in radiopharmaceuticals. The rule referenced other rules that no longer existed. In order to clarify the references required, no other rules are now referenced. All required references are listed under 12.00.32(a).

Authority for amendment of Rule 12.00.32(a): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

18. **The Basis and Purpose for the addition of Rule 14.00.05 and the deletion of Rule 14.00.90** is to relocate the list of facilities eligible to obtain an Other Outlet registration to the beginning of Rule 14.00.00. Rule 14.00.05 now includes federally qualified health centers, ambulatory surgery centers, medical clinics operated by hospitals, and hospices. These facility types were made eligible for Other Outlet registration during the 2012 Legislative Session under 12-42.5-102(25), C.R.S.

    Authority for the addition of Rule 14.00.05 and deletion of Rule 14.00.90: Sections 12-42.5-101, 12-42.5-102(25), 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

19. **The Basis and Purpose for the amendment to or deletions of 14.00.10(b) and (d)** is in (b) to clarify that Other Outlets may procure needed medications during emergency situations from other sources. Rule 14.00.10(d) is being deleted because federally qualified health centers were added into the list of facilities that qualify for Other Outlet registration during the 2012 Legislative Session under 12-42.5-102(25), C.R.S. Consequently, there is no longer a need to define them as a "community clinic."

    Authority for the amendment to or deletions of 14.00.10(b) and (d): Sections 12-42.5-101, 12-42.5-102(25), 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

20. **The Basis and Purpose for the amendments to Rules 14.00.80(d) and (e)(1)** is to add clarification that the a required "form" in 14.00.80(d) is actually an "inspection form" and to clarify how often the consultant pharmacist must inspect the federally qualified health centers, ambulatory surgery centers, medical clinics operated by hospitals, and hospices. These facilities became eligible for an Other Outlet registration during the 2012 Legislative Session under 12-42.5-102(25), C.R.S.

    Authority for the amendments to Rules 14.00.80(d) and (e)(1): Sections 12-42.5-101, 12-42.5-102(25), 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

21. **The Basis and Purpose for the amendment to 14.06.00(a)** is to remove the term "visitation" because it is redundant. The purpose of the visitation is for inspection and the Other Outlets are required to be inspected.

Authority for the amendment to Rule 14.06.00(a): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

22. **The Basis and Purpose for the amendments to Rule 14.07.00** is to correct typographical errors.

    Authority for the amendment to Rule 14.07.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

23. **The Basis and Purpose for the amendment to Rule 15.01.18(b)(5)** is to change the term "expired/lapsed" to "expired

    Authority for the amendment to Rule 15.01.18(b)(5): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

24. **The Basis and Purpose for the deletion of Rule 15.09.11(d)** is to delete the requirement for the Pharmacy Board to set a date as to when electronic pedigrees must be utilized. Section 12-22-805(2), C.R.S. required the Board to set this date. This law was deleted in the 2012 Legislative Session and it was not recodified to Title 12, Article 42.5, C.R.S. The current 15.09.11(d) will become 15.09.11(d).

    General Authority for the amendment to Rule 15.09.11(d): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-306(6) and 24-4-103, C.R.S.

25. **The Basis and Purpose for the amendments to 15.01.11(b) and 15.01.14(c)** is to extend the time a wholesaler has to submit an application and fee when it changes its designated representative. The current timeframe is fourteen days. The Board proposes to increase this time to thirty days.

    General Authority for the amendments to Rules 15.01.11(b) and 15.01.14(c): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-306(6) and 24-4-103, C.R.S.

26. **The Basis and Purpose for the amendments to 15.10.14(a) and (b)** is to effectuate the legislative changes enacted in 12-42.5-118(3)(b), C.R.S. These changes allow wholesalers that provide prescription drugs to a person responsible for the control of an animal to now receive non-controlled substance prescription orders orally as well as in writing. If the order is transmitted orally, the veterinarian must present the wholesaler with a written

prescription order within three business days. Requirements were also added regarding how the oral prescription order is to be retained.

Authority for the amendment to Rule 15.09.11(d): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

27. **The Basis and Purpose for the deletion of Rule 17.00.00** is to remove outdated requirements.

Authority for the deletion of Rule 17.00.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

28. **The Basis and Purpose for the amendments to Rules 18.00.10(j), 18.01.10(e)-(h), 18.02.00, 18.03.11(b), (d), and (e)** is to remove the reference to the Rehabilitation Evaluation Committee which was removed from the statute.

Authority for the amendments to 18.00.10(j), 18.01.10(e)-(h), 18.02.00, 18.03.11(b), (d), and (e): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

29. **The Basis and Purpose for the renumbering of the first instance of 18.01.12 to 18.01.11** is because there are two rules numbered 18.01.12. The first instance of the rule is to be renumbered to 18.01.11.

Authority for the amendments to 18.00.10(j), 18.01.10(e)-(h), 18.02.00, 18.03.11(b), (d), and (e): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

30. **The Basis and Purpose for the amendment to Rule 18.03.12** is to change the PHAO's Board notification requirement in the event of contractual noncompliance from 24 hours to the next business day. This corresponds to the contractual agreement with the vendor for the Pharmacy Peer Health Assistance Diversion Program.

Authority for the amendment to Rule 18.03.12: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

31. **The Basis and Purpose for the amendments to Rules 20.01.20(a)(3) and (4)** is to amend the language for the labeling of prescriptions that are centrally processed (where more than one pharmacy participates in the dispensing process). New language is proposed for (3) and the current language in (3) will be moved to (4). This change allows the pharmacies flexibility to

determine labeling issues. They will only need to detail how the labeling is done in the Policy and Procedure Manual.

Authority for the amendments to Rules 20.01.20(a)(3) and (4): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

32. **The Basis and Purpose for the amendments to Rules 21.00.20(a) and (b)** is to clarify that only in-state prescription drug outlets may distribute compounded products. This change states specifically that nonresident prescription drug outlets may not do so and may only ship dispensed prescriptions into Colorado pursuant to CSR 12-42.5-130(2).

    Authority for amendments to 21.00.20(a) and (b) : Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-130(2) and 24-4-103, C.R.S.

33. **The Basis and Purpose for the Amendments to 23.00.10(a)(1) and 23.00.70(g)** is to effectuate the change in name of the "Division of Registrations" to the "Division of Professions and Occupations" which occurred in the 2012 Legislative Session.

    Authority for amendments to 23.00.10(a)(1) and 23.00.70(g): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106 and 24-4-103, C.R.S.

34. **The Basis and Purpose for the deletion of Rule 23.00.20 and the addition of Rule 23.00.90** are to better clarify the entities and individuals who are exempt from reporting to the Electronic Prescription Drug Monitoring Program.

    Authority for Authority for amendments to 23.00.10(a)(1) and 23.00.70(g): Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-404(2) and 24-4-103, C.R.S.

35. **The Basis and Purpose of the addition of all parts of Rule 24.00.00, "Confidential Agreements"** is to set forth the notification requirements for a physical or mental illness or condition that impacts a pharmacist's or pharmacy intern's ability to practice pharmacy with reasonable skill and safety, consistent with Section 12-42.5-134, C.R.S., which was added during the 2012 legislative session. This new statute provides that a pharmacist or pharmacy intern who appropriately addresses his/her physical or mental illness or condition will not be subject to discipline for unprofessional conduct due to the health condition. Prior to the 2012 Sunset Process, the Pharmacy Practice Act defined unprofessional conduct to include having a physical or mental disability that rendered the licensee unable to

practice pharmacy with reasonable skill and safety. Pharmacists and pharmacy interns were subject to discipline by the Board due to having such a disability. Following the Sunset Review in 2012, the General Assembly amended the Pharmacy Practice Act to no longer include having such a physical or mental disability as grounds for discipline. Rather, a pharmacist or pharmacy intern is now able to address a physical or mental illness or condition without the stigma of a disciplinary action provided the pharmacist or pharmacy intern acts within the limitations created by that physical or mental illness or condition. A pharmacist or pharmacy intern would only be subject to disciplinary action if the pharmacist or pharmacy intern failed to comply with the limitations of a Confidential Agreement entered into pursuant to Section 12-42.5-134, C.R.S., failed to act within the limitations created by the physical or mental illness or condition, or failed to notify the Board of a physical or mental illness or condition that impacts a licensee's ability to practice pharmacy with reasonable skill and safety.

Authority for addition of all parts of Rule 24.00.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-123(1)(e), 12-42.5-134, Title 12, Article 42.5, Part 2, C.R.S. and 24-4-103, C.R.S.

36. **The Basis and Purpose for the addition of all parts of Rule 25.00.00, "Specialized Prescription Drug Outlets"** is to effectuate the 2012 legislative amendments. Section 12-42.5-117(11) C.R.S. authorizes registration of a prescription drug outlet that engages in the compounding, dispensing, and delivery of drugs and devices or provides pharmaceutical care to residents of a long-term care facility. The Board rule amendments are to set forth the requirements for the pre-registration inspection, registration, and operation of a specialized drug outlet, standards, scope of practice, records and record-keeping, and a policy and procedures manual, consistent with and as authorized by Section 12-42.5-117(11), C.R.S.

Authority for addition of all parts of Rule 25.00.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-117(11) and 24-4-103, C.R.S.

37. **Basis and Purpose of adoption of all parts of Rule 26.00.00, "Remote Pharmacy Practice":** is to effectuate the 2012 General Assembly legislative amendments set forth in Section 12-42.5-118(4),C.R.S. authorize performing "Initial Interpretation" and "Final Evaluation" at a location other than a registered prescription drug outlet or registered other outlet. The new Board rule defines Final Evaluation" and "Initial Interpretation" for purposes of remote pharmacy practice, establishes and clarifies equipment requirements for this type of

remote pharmacy practice, and authorizes conducting initial interpretations and final evaluations remotely as authorized by Section 12-42.5-118(4),C.R.S. Among other issues, the Board rule amendments establish requirements for security, protection of privacy, and a Policy and Procedure Manual.

Authority for addition of all parts of Rule 26.00.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-118(4) and 24-4-103, C.R.S.

38. **Basis and Purpose for the addition of all parts of Rule 27.00.00, "Hospital Satellite Pharmacies"** is to effectuate the 2012 General Assembly legislative amendments set forth in Section 12-42.5-117(10), C.R.S. which require the registration of a hospital satellite pharmacy, defined as one located in a facility that is under the same management and control as the building or site where a hospital's primary prescription drug outlet is located, but has a different address than the primary prescription drug outlet. The Board rule amendments set forth the requirements for registration and operation of a hospital satellite pharmacy, consistent with the 2012 legislative amendments. The new Board rules set a distance limit for a hospital satellite pharmacy of no more than 1 mile from the main entrance to the building which houses the primary prescription drug outlet. The amendments to the Board rules establish the method for applying for registration, the requirement of pre-registration inspection, responsibilities of the pharmacist manager, record-keeping requirements, staffing, manner of distribution of drugs, inventory, requirements that pertain to the compounding/dispensing area and adjacent area, minimum equipment, reference library, Board inspections, hours of operation and security.

Authority for addition of all parts of Rule 27.00.00: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, 12-42.5-117(10) and 24-4-103, C.R.S.

39. The following table includes rules that reference statutory cites in Title 12, Article 22, C.R.S. which was relocated to Title 12, Article 42.5, C.R.S. during the 2012 Legislative Session, the prior citations, and the recodified citations as they appear in the amended rules.

Authority for these changes in statutory citation: Sections 12-42.5-101, 12-42.5-105, 12-42.5-106, and 24-4-103, C.R.S.

INDEX FOR BOARD RULES WHERE ONLY CITATION NUMBERS ARE CHANGED (DOES NOT INCLUDE SUBSTANTIVE ISSUES IDENTIFIED IN ABOVE BASIS AND PURPOSE)

Rule Number Old Citation 12-22-___ New Citation 12-42.5____

1.00.24	(Sec 12-22-)128(2)	(Sec 12-42.5-)128(2)
2.00.10(a)	121(12)	118(11)
3.00.60	124	122
3.00.10	122(2)	120(2)
3.00.20	125	123
3.00.60	124	122
3.00.70	119(5)	116(5) (not only change in this section)
3.00.87(a)(6)	123(2)	121(2)
3.03.10	123(2)	121(2)
5.00.01(b) and (c)	Title 12, Art. 22	Title 12, Art. 42.5
5.00.40	119	116
5.01.31	102(30.2)	102(35)
7.00.10	Title 12, Article 22	Name change Title 12, Article 42.5
7.00.30(c)	128(2)	128(2)
12.00.10	Title 12, Art. 22	Title 12, Art. 42.5
12.00.32(a)	Title 12, Art. 22	Title 12, Art. 42.5
13.00.13	22-101 et seq.	42.5-101 et seq.
14.00.10	120(1)(e)	117(1)(d)
15.01.11(a)(8)(i)	803	304
18.00.10(b)(3)	605(3)	204(3)
18.00.10(f)	Art. 22, Part 6	Art 42.5, Part 2
18.03.10(b)(3)	605(3)	204(3)
20.00.80(a)	123	121
21.00.20(b)	120(9); 121(18)(a) and (b)(I) and (II)	117(9), 118(15)(a) and (b)(I) and (II)
21.10.60(h)	128(2)	128(2)
21.11.10 (a)(1) and (b)(1)	123	121
21-21-10(i)	128(2)	128(2)
21.21.70(a)(1) and (b)(1)	123	121
23.00.10(a)(1)	Division of Registrations	Division of Professions and Occupations

23.00.10(b)	705(5)	404(5)