BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of ARM 24.174.401 fee schedule, 24.174.403 change in address, 24.174.805 change of pharmacist-in-charge, 24.174.813 class IV facility, 24.174.1003 identification of pharmacist-in-charge, 24.174.1201 wholesale drug distributor, 24.174.1302 telepharmacy operations, 24.174.1412 dangerous drugs, and the adoption of NEW RULES I through X cancer drug repository, and NEW RULES XI through XIV clinical pharmacist practitioner	)))))))))))))	NOTICE OF AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On September 23, 2010, the Board of Pharmacy (board) published MAR notice no. 24-174-60 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 2041 of the 2010 Montana Administrative Register, issue no. 18.

2. On October 14, 2010, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Several comments were received by the October 22, 2010, deadline.

3. The board has thoroughly considered the comments received. A summary of the comments received and the board's responses are as follows:

ARM 24.174.401: Fee Schedule

COMMENT 1: One commenter opined that while the application process could be extensive, setting the initial registration and renewal fees too high for clinical pharmacist practitioners would discourage applicants. The commenter suggested alternate fees.

RESPONSE 1: The board is required under 37-1-134, MCA, to set and maintain fees commensurate with actual costs. The board proposed the fee according to projected costs, but will amend the fees in a future rulemaking project if the estimates prove inaccurate.

COMMENT 2: A number of commenters opposed the board charging any fee for either initial or renewal licensure of family planning limited pharmacies.

RESPONSE 2: The board notes that the proposed amendment would only change the facility name, with no change to the $75 fee. Since the board did not propose to amend the fee in the original rulemaking notice, it is unable to alter the fee in the final notice. The board is amending the rule exactly as proposed.

ARM 24.174.813: Family Planning Limited Pharmacy Facility

COMMENT 3: Several commenters opposed the licensure and renewal fees, as well as requiring a pharmacist-in-charge principally because such clinics – whether government or private operations – survive on tight budgets that cannot accommodate the additional expense. The commenters suggested that a pharmacist-in-charge would offer little in additional public safety regarding prepackaged products, and the expense would threaten the programs themselves.

RESPONSE 3: This class of pharmacy historically required pharmacists, just as other forms of pharmacies. Pharmacists' roles through the 1990s included assuring proper labeling and prescription preparation, as well as appropriate patient counseling. Over time, regulation and oversight abated leaving only one such licensed facility in the state. Formerly, such clinics were limited to contraceptive products, but now the rule envisions expedited partner therapy for chlamydia and gonorrhea, as well as onsite drug storage.

The board does not intend to restrict health care access through these facilities, but to return to an appropriate level of regulation balancing public safety and accessibility. That balance necessitates a pharmacist's involvement in this class of pharmacy, just as in other classes of pharmacies. However, following comment consideration, the board is not amending this rule at this time.

COMMENT 4: A few commenters stated that the funding systems of these pharmacies conflict with a blanket rule that prohibits charging for the drugs.

RESPONSE 4: The proposed amendments would continue the current rule's provision that drugs be offered at no cost. Considering the commenters' statements that they must be allowed to charge for drugs in some instances, the board agreed to delete the offending paragraph. However, following consideration of all comments, the board is not amending this rule at this time.

COMMENT 5: Commenters generally favored expanding services to include expedited patient-delivered partner therapy for chlamydia, but one commenter opined that the standard of care prohibits such therapy for gonorrhea.

RESPONSE 5: The board notes that the Center for Disease Control (CDC) has established that gonorrhea may be treated by partner therapy. However, following further comment consideration, the board is not amending this rule at this time.

ARM 24.174.1412: Additions, Deletions, and Rescheduling of Dangerous Drugs

COMMENT 6: Two commenters applauded the board's effort to update the schedule of drugs, but suggested setting forth the complete schedule in both the administrative rules and the Montana Code Annotated (MCA), rather than simply adopting the federal schedule by reference. The commenters also advised that the administrative rules and the MCA would be more useable to law enforcement if both exactly mirrored the current federal schedule of drugs.

RESPONSE 6: The board considered the points of view of those in law enforcement who rely upon the Montana Criminal Code, Title 45, chapter 9, that cross-references the schedules of drugs found in the Controlled Substances Act at Title 50, chapter 32, part 2. Of course, only the Legislature can update a Montana statute. However, the Controlled Substances Act empowers the board to administer the chapter and amend the list of schedules by rulemaking at 50-32-103, MCA, and mandates timely updates following federal action to designate, reschedule, or delete a controlled substance at 50-32-203, MCA. Finding it unwieldy, the board opted not to repeat the full schedules in rule. After a period of inattention, the board is committed to regularly updating the schedules in the future, to avoid inconsistencies between the federal schedules and Montana's parallel schedules, which should serve the interests of law enforcement and the public.

NEW RULE III: Acceptable Cancer Drugs

COMMENT 7: One commenter observed that a change agreed upon during the drafting process was not included in the proposed new rule. The commenter suggested amending (2) to read, "Any cancer drug donated to the program cannot be used past its expiration date."

RESPONSE 7: The board agreed that the suggested language was offered and accepted in the drafting stage, but was inadvertently omitted from the proposed version. The board is amending New Rule III accordingly.

COMMENT 8: A commenter suggested clarifying that acceptable cancer drugs are only those approved by the FDA for use in the United States.

RESPONSE 8: The board discussed whether it was likely that an unapproved cancer drug could enter the repository system and observed that clinical trials of unapproved drugs are regulated by the FDA. While it is possible for a foreign drug unapproved for use in the United States to be offered to the repository, the likelihood seems remote. Consequently, the board is adopting that portion of the rule as proposed, but will monitor the issue and take responsive action if and when required.

NEW RULE VII: Record-Keeping Requirements

COMMENT 9: A commenter suggested the board clarify that the perpetual recordkeeping requirements in (1) and (2) apply only to donated cancer drugs.

RESPONSE 9: The board agrees and is amending the new rule accordingly.

NEW RULE XI: Definitions

COMMENT 10: One commenter suggested improving New Rule XI by clearly defining "clinical pharmacist practitioner" and adding an official abbreviation of CPP.

RESPONSE 10: The board concluded that defining "clinical pharmacist practitioner" in rule is unnecessary, as an adequate definition exists in statute at 37-7-306, MCA. While statutory title protection exists for some professionals such as nurses (37-8-408, MCA), physician assistants (37-20-303, MCA), and social workers (37-22-305, MCA), it does not in the case of clinical pharmacist practitioners. Consequently, the board declined to add an official abbreviation of the title in rule.

COMMENT 11: A commenter suggested amending (2) to revise the minimum time spent in clinical pharmacist practice from 50 to 30 percent and establish a weekly practice minimum in hours, rather than a percentage to manage instances where a pharmacist many not work full-time.

RESPONSE 11: In writing the rule, the board incorporated the experience of New Mexico and North Carolina. Additionally, 37-7-201(2)(e), MCA, requires the board to gain the concurrence of the Board of Medical Examiners in "defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner." Having gained the required concurrence, the board is adopting New Rule XI exactly as proposed.

NEW RULE XII: Requirements to Become a Clinical Pharmacist Practitioner

COMMENT 12: A commenter cautioned the board that setting the experience and credentialing standards for clinical pharmacist practitioners too high would restrict the registration to an elite few, which could then eliminate qualified clinicians and impact payments to pharmacists from third party payors. The commenter suggested the board adopt standards based on the North Carolina model.

RESPONSE 12: As noted above, the Legislature requires the board to develop rules on clinical pharmacist practitioner standards in concurrence with the Board of Medical Examiners. Having gained the required concurrence, the board is adopting New Rule XII exactly as proposed.

COMMENT 13: A commenter posited that a clinical pharmacist practitioner must work under a collaborative practice agreement, but such an agreement should not be a prerequisite to registration. The commenter believed this would engender administrative and logistical problems in initiating a new registered practice.

RESPONSE 13: See response 12 above.

4. The board received no comments regarding ARM 24.174.403, 24.174.805, 24.174.1003, 24.174.1201, 24.174.1302, NEW RULES I (24.174.1501), II (24.174.1502), IV (24.174.1504), V (24.174.1505), VI (24.174.1506), VIII (24.174.1508), IX (24.174.1509), X (24.174.1510), XIII (24.174.527), and XIV (24.174.528).

5. The board has amended ARM 24.174.401, 24.174.403, 24.174.805, 24.174.1003, 24.174.1201, 24.174.1302, and 24.174.1412 exactly as proposed.

6. The board has adopted NEW RULE I (24.174.1501), NEW RULE II (24.174.1502), NEW RULE IV (24.174.1504), NEW RULE V (24.174.1505), NEW RULE VI (24.174.1506), NEW RULE VIII (24.174.1508), NEW RULE IX (24.174.1509), NEW RULE X (24.174.1510), NEW RULE XI (24.174.525), NEW RULE XII (24.174.526), NEW RULE XIII (24.174.527), and NEW RULE XIV (24.174.528) exactly as proposed.

7. The board has adopted NEW RULE III (24.174.1503) and NEW RULE VII (24.174.1507) with the following changes, stricken matter interlined, new matter underlined:

NEW RULE III (24.174.1503) ACCEPTABLE CANCER DRUGS (1) and (2) remain as proposed.

(3) Any cancer drug donated to the program cannot be used past its expiration date.

NEW RULE VII (24.174.1507) RECORD-KEEPING REQUIREMENTS (1) A pharmacy or facility must maintain a perpetual inventory log book of all donated cancer drugs received, dispensed, or distributed.

(2) The perpetual inventory log book must contain the following information regarding all donated cancer drugs received, dispensed, or distributed:

(a) through (2)(m) remain as proposed.

8. The board did not amend ARM 24.174.813 as proposed.

BOARD OF PHARMACY
LEE ANN BRADLEY, RPH, PRESIDENT

/s/ DARCEE L. MOE
Darcee L. Moe
Alternate Rule Reviewer

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State December 13, 2010