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

In the matter of the proposed amendment) NOTICE OF PUBLIC HEARING
of ARM 24.174.301 definitions, 24.174.401	ON PROPOSED AMENDMENT
fee schedule, 24.174.1122 ambulatory)
surgical facilities, and 24.174.2104)
continuing education)

TO: All Concerned Persons

- 1. On April 3, 2008, at 9:00 a.m., a public hearing will be held in room 439, 301 South Park Avenue, Helena, Montana to consider the proposed amendment of the above-stated rules.
- 2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy (board) no later than 5:00 p.m., on March 28, 2008, to advise us of the nature of the accommodation that you need. Please contact Ronald J. Klein, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2371; Montana Relay 1-800-253-4091; TDD (406) 444-2978; facsimile (406) 841-2305; e-mail dlibsdpha@mt.gov.
- 3. The rules proposed to be amended provide as follows, stricken matter interlined, new matter underlined:
- <u>24.174.301 DEFINITIONS</u> In addition to the terms defined in 37-7-101, MCA, the following definitions apply to the rules in this chapter.
- (1) "Ambulatory surgical facility " means "outpatient center for surgical services" as defined at 50-5-101, MCA.
 - (2) through (25) remain the same but are renumbered (1) through (24).
 - (25) "Outpatient center for surgical services" is as defined at 50-5-101, MCA.
 - (26) through (36) remain the same.

AUTH: 37-1-131, 37-7-201, 50-32-314, MCA

IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-321, 37-7-406, 37-7-603, 37-7-604, 37-7-605, 50-32-314, MCA

24.174.401 FEE SCHEDULE

- (1) through (19) remain the same.
- (20) Ambulatory surgical facility Outpatient center for surgical services (original or renewal) 75
 - (21) remains the same.

AUTH: 37-1-134, 37-7-201, 50-32-314, MCA

IMP: 37-1-134, 37-7-201, 37-7-302, 37-7-321, 37-7-604, 37-7-605, 37-7-

703, 50-32-314, MCA

<u>24.174.1122 AMBULATORY SURGICAL FACILITIES OUTPATIENT</u> <u>CENTERS FOR SURGICAL SERVICES</u> (1) The board shall annually register and inspect all ambulatory surgical facilities <u>outpatient centers for surgical services</u> in Montana, regardless of pharmacy status.

- (2) In an ambulatory surgical facility <u>outpatient center for surgical services</u> without an on-site pharmacy, drug distribution must be directed by a physician or consulting pharmacist licensed to practice in Montana and who is responsible for the security, storage, and distribution of drugs within the facility.
 - (3) and (4) remain the same.

AUTH: 50-32-314, MCA IMP: 50-32-314, MCA

<u>REASON</u>: The board determined it is reasonably necessary to amend ARM 24.174.301, 24.174.401, and 24.174.1122 to match terminology used in statute. The 2007 Montana Legislature enacted Chapter 502, Laws of 2007 (Senate Bill 153), an act revising professional and occupational licensing laws. The bill was signed by the Governor on May 16, 2007, and became effective on October 1, 2007. This legislation changed the term "ambulatory surgical facility" to "outpatient center for surgical services." The rules are being amended to reflect current terminology.

<u>24.174.2104 REGISTERED PHARMACIST CONTINUING EDUCATION - REQUIREMENTS</u> (1) remains the same.

- (2) The board will require 1.5 CEU for each fiscal year, July 1 to June 30.
- (a) This requirement will not pertain to a pharmacist who is applying for his or her the first license renewal after initial licensure in Montana.
- (i) Pharmacists previously licensed in another state are not exempt from this requirement.
- (b) Only an additional 1.5 CEU may be accumulated and applied to the following year. Each pharmacist licensed in Montana shall complete 1.5 CEU during each fiscal year period. No CEU credit may be carried over from a preceding fiscal year.
 - (c) and (3) remain the same.
- (4) Every pharmacist is responsible for maintaining in their personal files certificates or records of credit from acceptable continuing education activities attended and/or completed. Such records shall be maintained for the preceding two fiscal years.

AUTH: 37-1-319, MCA IMP: 37-1-306, MCA

<u>REASON</u>: It is reasonable and necessary to amend this rule and modify the registered pharmacist continuing education (CE) requirements. The board is

amending this rule to clarify the time period for CE to be obtained for license renewal and eliminate the carryover of CE units to the next renewal period. The board is proposing these changes to ensure that each Montana licensed pharmacist obtains the required CE during each licensure period and reduce the possibility of fraud by licensees claiming the same CE for two consecutive licensure periods.

The board is also amending (2)(a) to clarify that the first-renewal CE exemption does not apply to pharmacists previously licensed in another state. It has always been the board's intent that only pharmacists receiving their initial licensure as a pharmacist in Montana be exempt from CE at the first renewal cycle. The board is amending (2)(a) to clarify the exemption and address questions and confusion from several licensees at each renewal.

The board is adding (4) to set forth individual pharmacist CE record keeping requirements. Following recent CE audit experiences, the board concluded that better record keeping standards are necessary to enable board staff to obtain the necessary documentation and adequately conduct CE compliance audits. The rule is further amended to substitute gender neutral terms for gender specific language.

- 4. Concerned persons may present their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2305, or by e-mail to dlibsdpha@mt.gov, and must be received no later than 5:00 p.m., April 11, 2008.
- 5. An electronic copy of this Notice of Public Hearing is available through the department and board's site on the World Wide Web at www.pharmacy.mt.gov. The department strives to make the electronic copy of this Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the department strives to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems, and that technical difficulties in accessing or posting to the e-mail address do not excuse late submission of comments.
- 6. The Board of Pharmacy maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this board. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies the person wishes to receive notices regarding all Board of Pharmacy administrative rulemaking proceedings or other administrative proceedings. The request must indicate whether e-mail or standard mail is preferred. Such written request may be sent or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, faxed to the office at (406) 841-2305, e-mailed to dlibsdpha@mt.gov, or made by completing a request form at any rules hearing held by the agency.

- 7. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified on January 28, 2008, by regular mail.
- 8. Mike Fanning, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY JAMES CLOUD, CPHT, 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 March 3, 2008