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

In the matter of the amendment of 24.174.301 definitions, 24.174.1201 wholesale drug distributor licensing, 24.174.2107 registered pharmacist continuing education and the adoption of NEW RULES I use of contingency kits, II definitions, III information required for submission, IV electronic format required for the transmission of information, V requirements for submitting prescription registry information, VI failure to report prescription information, VII registry information review and unsolicited patient profiles, VIII access to prescription drug registry information, IX registry information retention, X advisory group, XI prescription drug registry fee, XII release of prescription drug registry information to other entities, and XIII interstate exchange of registry information	)))))))))))))))))))	NOTICE OF AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On December 8, 2011, the Board of Pharmacy (board) published MAR notice no. 24-174-63 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 2606 of the 2011 Montana Administrative Register, issue no. 23.

2. On January 3, 2012, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Several comments were received by the January 12, 2012, deadline.

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

NEW RULE I Use of Contingency Kits in Certain Institutional Facilities:

COMMENT 1: One commenter opposed (1)(b), that allows the pharmacist and designated practitioner or facility committee to determine content and quantity of

drugs in contingency kits. The commenter opined that if the board will not limit the contents of the kits, an opening for unlicensed pharmacy practice will be created.

RESPONSE 1: The board agrees that the potential exists for institutions to expand the use of contingency kits beyond the limited role the board envisions. However, the issue is scheduled for an upcoming board meeting, and if experience shows that contingency kits exceed reasonable bounds, the board will revisit this rule and curtail any excesses.

COMMENT 2: One commenter supported contingency kits in long-term care facilities and noted that lack of timely access to drugs creates potential harm to the patient. The commenter endorsed permitting emergency kits (e-kits) for truly emergent medications supplemented by contingency kits, subject to specific security and storage recommendations, based on the commenter's professional experience. The commenter also suggested changing "pharmacist" in (1)(f)(ii) to "pharmacy," limiting the kit to a maximum of 75-100 medications, and amending the rule to provide for inspection more frequently than annually, greater control by the supplying pharmacy, and defined consequences for improperly removing medications.

RESPONSE 2: The board agrees that the word "pharmacist" in (1)(f)(ii) should be changed to "pharmacy," and is amending the rule accordingly. The board concluded that the provision on inspection frequency is adequate since the annual inspection is just a minimum requirement and the rule allows the professionals involved to conduct inspections more frequently, should they choose to do so.

The board concurs that the facility pharmacist should have greater control and be involved when staff accesses the contingency kit. Noting that the comments about contingency kit contents are similar to those in Comment 1, the board concluded that it will monitor institutions' experience with the rule as proposed, and make changes as may be necessary.

COMMENT 3: One commenter stated that an individual accessing the contingency kit should be required to notify the pharmacy or pharmacist-on-call to gain authorization to access the kit. The commenter also said that annual inspections are too infrequent and should be every other month or more often.

RESPONSE 3: As noted in Response 2, the board concluded that the proposed language on inspection frequency is adequate, but is amending this rule to require a pharmacist's involvement if a staff person accesses a contingency kit.

COMMENT 4: One commenter noted that DPHHS is answerable to the Federal Centers for Medicare Services regarding long-term care facilities' management of pharmaceuticals and recounted a prior discussion with a DPHHS representative in which the commenter presented concerns about medication delivery in long-term care facilities. The commenter opined that allowing contingency kits may or may not rectify untimely ordering, delivery, or administration of medications, and that certain difficulties may be overcome by better procedures regarding admission policies and clarity of pharmacy obligations. Recognizing contingency kits could aid patient care,

the commenter restated that the current language of (1)(b) could allow an unlicensed pharmacy without board oversight.

RESPONSE 4: This commenter raised concerns similar to those regarding contents and quantity of drugs included in contingency kits. The board expects to monitor this issue, discuss it at an upcoming board meeting, and propose such rule amendments as may be required, based on actual experience.

New Rules II through XIII Prescription Drug Monitoring Program:

COMMENT 5: Several commenters strongly supported the adoption of these new rules as drafted. One commenter recounted the longstanding work of the Montana Attorney General's office to reduce prescription drug abuse in Montana and secure passage of House Bill 83, which created the prescription drug registry.

RESPONSE 5: The board acknowledges and appreciates the cooperative effort of all parties involved in both the establishment of the registry and the promulgation of these new rules.

COMMENT 6: One commenter supported the new rules, but was concerned about requiring pharmacies to report the names of individuals picking up the controlled substance prescriptions and the ability of participating pharmacies to provide this information by the March 1, 2012 implementation date. The commenter observed that differences in computer processing systems may require reprogramming, which would likely not be completed by the deadline. The commenter stated that the additional information field will place an additional administrative burden on pharmacists processing controlled substance prescriptions and asked the board to work cooperatively with pharmacies to address the concerns.

The commenter also opposed assessing any fees on pharmacies to fund the program and urged the board to seek funding from state and/or federal sources rather than participants. The commenter suggested that before charging participants, the board should seek funding from grants available through the National All Schedules Prescription Electronic Reporting Act and the Harold Rogers Program.

RESPONSE 6: The board notes that an earlier draft of the rules did include a requirement that pharmacies report to the registry the names of individuals who actually pick up the controlled substance prescriptions, but that the rules as proposed do not contain that requirement. Given that that field is no longer required, the board concluded that the commenter's concerns about costs and adapting computer systems are now moot.

Noting that the board received a grant from the Harold Rogers Program and that the National All Schedules Prescription Electronic Reporting is currently unfunded, the board concluded that it has tapped the grant resources currently available. The board determined that it will still need to charge user fees to operate the system after the grant is exhausted, and until the legislature can consider the adequacy of the $15 annual fee.

COMMENT 7: One commenter suggested the board exempt institutional/hospital and long-term care pharmacies from reporting, since medications are either used onsite or, in some emergency rooms, dispensed only in limited quantities. The commenter stated that hospital information systems are not geared to capture and report the required information. The commenter encouraged simple access to the program for emergency rooms, so locum tenens physicians and/or emergency room nurses have access.

The commenter also noted the facility's proximity to North Dakota and the transient population of oilfield workers in the community. The commenter suggested developing an information sharing system with other states to address the large number of patients with irregular home addresses who lack a regular patient-provider relationship and use multiple pharmacies.

RESPONSE 7: The board concluded that the concerns about an exemption for institutional/hospital and long-term care pharmacies is addressed in the reporting exemption for "a person who is hospitalized" in 37-7-1503(2)(b), MCA. Noting that the statute provides no exemption for reporting by emergency rooms, the board concluded that each certified pharmacy that dispenses drugs to patients in Montana shall submit information to the registry.

The board recognizes the special cases of locum tenens emergency room physicians, and is confident that registry staff will promptly process applications for access to the registry. However, those physicians, like all others, must apply for access. While nurses without prescriptive authority are not permitted direct registry access under 37-7-1506, MCA, New Rule VIII permits access by a "practitioner's authorized agent," which would allow an emergency room nurse access to the registry. The registry is permitted to share information with other states, 37-7-1506(1)(g), MCA, and under New Rule XIII, the board contemplates entering into agreements with sister states to share information.

The board is correcting an internal citation error in New Rule VIII(2)(c)(iv)(B). In the proposal notice, the citation should have referenced New Rule VII, and should not have indicated the rule's projected final rule number. This amendment provides the number being assigned to New Rule VII within this final notice.

4. The board has amended ARM 24.174.301, 24.174.1201, and 24.174.2107 exactly as proposed.

5. The board has adopted New Rules II (24.174.1701), III (24.174.1702), IV (24.174.1703), V (24.174.1704), VI (24.174.1705), VII (24.174.1706), IX (24.174.1709), X (24.174.1711), XI (24.174.1712), XII (24.174.1713), and XIII (24.174.1715) exactly as proposed.

6. The board has adopted New Rules I (24.174.1115) and VIII (24.174.1708), with the following changes, stricken matter interlined, new matter underlined:

NEW RULE I (24.174.1115) USE OF CONTINGENCY KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) through (1)(f)(i) remain as proposed.

(ii) the name, address, and telephone number of the supplying ~~pharmacist~~ pharmacy.

(2) Drugs shall be removed from kits only: ~~by the supplying pharmacist or by authorized nursing personnel pursuant to a valid drug order or during inspection of the kit.~~

(a) by the supplying pharmacist; or

(b) by authorized nursing personnel pursuant to a valid drug order and reviewed by a pharmacist; or

(c) during inspection of the kit.

(3) through (6) remain as proposed.

NEW RULE VIII (24.174.1708) ACCESS TO PRESCRIPTION DRUG REGISTRY INFORMATION (1) through (2)(c)(iv)(A) remain as proposed.

(B) that necessary for legitimate inquiries under ARM ~~24.174.1705~~ 24.174.1706;

(v) through (8) remain as proposed.

BOARD OF PHARMACY
LEE ANN BRADLEY, R.PH., 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 February 27, 2012