NOTICES OF RULEMAKING DOCKET OPENING

The Administrative Procedure Act (APA) requires the publication of Notices of Rulemaking Docket Opening when an agency opens a rulemaking docket to consider rulemaking. Under the APA effective January 1, 1995, agencies must submit a Notice of Rulemaking Docket Opening before beginning the formal rulemaking process.

NOTICE OF RULEMAKING DOCKET OPENING

BOARD OF PHARMACY

Editor's Note: The following Notice of Rulemaking Docket Opening was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2269.)

[R12-167]

1. Title and its heading: 4, Professions and Occupations
Chapter and its heading: 23, Board of Pharmacy
Articles and their headings: 6, Permits and Distribution of Drugs
Section numbers: R4-23-604, R4-23-605 (Sections may be added, deleted, or modified as necessary.)

2. Subject matter of the proposed rule:

In 2008 the 48th Legislature passed HB 2020. HB 2020 removed the requirement that only a pharmacist could manufacture a drug and specifically allowed a person who is not a pharmacist to manufacture a drug if that person possessed a permit to manufacture drugs from the Board of Pharmacy. The Board has a rule (R4-23-604 Resident Drug Manufacturer) that implements the statutory requirements for drug manufacturing. Before the Board could move to make changes to R4-23-604 necessitated by HB 2020, the Governor imposed a rulemaking moratorium that lasted until September 2011. The Board is now ready to make the necessary changes to R4-23-604 to bring the rule into compliance with the statutory changes made in HB 2020. The Board has also determined that R4-23-605 Resident Drug Wholesaler Permit needs to be amended to remove the requirement that a pharmacy or licensee who is returning a drug to a drug wholesaler must provide the lot number and expiration date of the drug being returned on the return paperwork. Since a drug wholesaler does not have to provide a lot number and expiration date of a drug on the invoice when the wholesaler delivers the drug to the pharmacy, the pharmacies do not see why a pharmacy should be required to provide a lot number and expiration date of a drug when the drug is returned to the wholesaler. The Board agrees with the pharmacies, and intends to remove the lot number and expiration date requirement.

The rulemaking will amend R4-23-604 Resident Drug Manufacturer by removing all references that require a pharmacist-in-charge in a drug manufacturing operation. Those references are in R4-23-604(B)(9) and (12), (D), (H)(1)(d), (J), and (O). The rulemaking will amend R4-23-605 Resident Drug Wholesaler Permit by removing the requirement for a lot number and expiration date in subsection (H)(3)(a).

The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The agency docket number, if applicable:
R1204

3. A citation to all published notices relating to the proceeding:
None

4. Name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Arizona Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Telephone: (602) 771-2744

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

5. The time during which the agency will accept written comments and the time and place where oral comments may be made:

The Board will accept written comments Monday through Friday, 8:00 a.m. to 5:00 p.m. Oral comments may be made at the Board office Monday through Friday, 8:00 a.m. to 4:30 p.m.

Location: Arizona Board of Pharmacy
1616 W. Adams St., Suite 120
Phoenix, AZ 85007

Mail: P.O. Box 18520
Phoenix, AZ 85005

Written and oral comments will be accepted until the close of record on a date and time as yet undetermined.

6. A timetable for agency decisions or other action in the proceeding:

None