

## NOTICES OF SUBSTANTIVE POLICY STATEMENTS

The Administrative Procedure Act requires the publication of substantive policy statements issued by agencies (A.R.S. § 41-1013(B)(14)). Substantive policy statements are written expressions which inform the general public of an agency's current approach to rule or regulation practice. Substantive policy statements are advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that a substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement.

### NOTICE OF SUBSTANTIVE POLICY STATEMENT

#### BOARD OF PHARMACY

[M06-418]

**1. Title of the substantive policy statement and the substantive policy statement number by which the policy statement is referenced:**

Pharmacist-in-charge at a Drug Manufacturer Compliance Policy Guide SPS09

**2. Date the substantive policy statement was issued and the effective date of the policy statement if different from the issuance date:**

September 20, 2006

**3. Summary of the contents of the substantive policy statement:**

This policy statement provides a guide to manufacturers and pharmacists of the Board's interpretation of A.R.S. 32-1961(A) and A.A.C. R4-23-604(H)(1)(d) and (J)(2), specifically how many hours per week a pharmacist should be employed when the manufacturing process occurs 24/7.

**4. A statement as to whether the substantive policy statement is a new statement or a revision:**

This is a new policy statement.

**5. The name, address, and telephone number of the person to whom questions and comments about the substantive policy statement may be directed:**

Name: Hal Wand, Executive Director  
Address: Board of Pharmacy  
4425 W. Olive Avenue, Suite 140  
Glendale, AZ 85302  
Telephone: (623) 463-2727  
Fax: (623) 934-0583

**6. Information about where a person may obtain a copy of the substantive policy statement and the costs for obtaining the policy statement:**

Copies of this policy statement may be obtained from the person listed above for \$0.25 per page.