**[Ariz. Rev. Stat. § 32-1963.01.]**

## § 32-1963.01. Substitution for prescription drugs or biological products; requirements; label; definitions: Pharmacy -- Regulation

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection E of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. A pharmacist may substitute a biological product for a prescribed biological product only if all of the following conditions are met:

1. The United States food and drug administration has determined the substituted product to be an interchangeable biological product.

2. The prescribing physician does not designate in writing or electronically that substitution is prohibited in a manner pursuant to subsection E of this section.

3. The pharmacy informs the patient or person presenting the prescription of the substitution pursuant to subsection C of this section.

4. Within five business days after dispensing a biological product, the dispensing pharmacist or the pharmacist's designee makes an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using fax, telephone, electronic transmission or other prevailing means, except that communication is not required if one of the following applies:

(a) There is no interchangeable biological product approved by the United States food and drug administration for the product prescribed.

(b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

5. The pharmacy retains a record of the biological product dispensed pursuant to section 32-1964, subsection A.



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C. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug or biological product prescribed and the generic equivalent drug or interchangeable biological product, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug or interchangeable biological product.

2. The transaction is not subject to third-party reimbursement.

D. The pharmacist shall place on the container the name of the drug or biological product dispensed followed by the words "generic equivalent for" or "interchangeable biological product for" followed by the brand or trade name of the product that is being replaced by the generic equivalent drug or interchangeable biological product. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

E. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

F. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

G. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug or interchangeable biological product or to substitute any specific generic equivalent drug or interchangeable biological product for a brand name drug or biological product against the professional judgment of the pharmacist or the order of the prescriber.

H. The liability of a pharmacist in substituting according to this section is no greater than that incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

I. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic equivalent drug or interchangeable biological product has shown that:

1. All products dispensed have an expiration date on the original package.

2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs or biological products.



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J. The board shall maintain on its public website a link to the current list of each biological product determined by the United States food and drug administration to be an interchangeable biological product.

K. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

L. For the purposes of this section:

1. "Biological product" has the same meaning prescribed in 42 United States Code section 262.

2. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.

3. "Formulary" means a list of medicinal drugs.

4. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the United States food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

5. "Interchangeable biological product" means a biological product that either:

(a) The United States food and drug administration has licensed and determined meets the safety standards for determining interchangeability pursuant to 42 United States Code section 262(k)(4).

(b) Is determined to be therapeutically equivalent as set forth in the latest edition of the supplement to the United States food and drug administration's approved drug products with therapeutic equivalence evaluations.



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