REFERENCE TITLE: prescription orders; biological products; substitution

State of Arizona
Senate
Fifty-first Legislature
First Regular Session
2013

SB 1438

Introduced by
Senators Ward: Barto; Representative Brophy McGee

AN ACT

AMENDING SECTIONS 23-908 AND 32-1963.01, ARIZONA REVISED STATUTES; RELATING TO THE STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 23-908, Arizona Revised Statutes, is amended to read:

23-908. Injury reports by employer and physician; schedule of fees; violation; classification

A. Every employer THAT IS affected by this chapter, and every physician who attends an injured employee of such employer, shall file with the commission and the employer's insurance carrier from time to time a full and complete report of every known injury to the employee arising out of or in the course of his employment and resulting in loss of life or injury. Such report shall be furnished to the commission and such insurance carrier at times and in the form and detail the commission prescribes, and the report shall make special answers to all questions required by the commission under its rules.

B. The commission shall fix a schedule of fees to be charged by physicians, physical therapists or occupational therapists attending injured employees and, subject to subsection C of this section, for prescription medicines required to treat an injured employee under this chapter. The commission shall annually review the schedule of fees.

C. If a schedule of fees for prescription medicines adopted pursuant to subsection B of this section includes provisions regarding the use of generic equivalent drugs, those provisions shall comply with section 32-1963.01, subsections A and C through ~~K~~ M. If the commission considers the adoption of fee schedule provisions that involve specific prices, values or reimbursements for prescription drugs, the commission shall base the adoption on studies or practices that are validated and accepted in the industry, including the applicability of formulas that use average wholesale price, plus a dispensing fee, and that have been made publicly available for at least one hundred eighty days before any hearing conducted by the commission.

D. Notwithstanding section 12-2235, information obtained by any physician or surgeon examining or treating an injured person shall not be considered a privileged communication, if such information is requested by interested parties for a proper understanding of the case and a determination of the rights involved. Hospital records of an employee concerning an industrial claim shall not be considered privileged if requested by an interested party in order to determine the rights involved. Medical information from any source pertaining to conditions unrelated to the pending industrial claim shall remain privileged.

E. When an accident occurs to an employee, the employee shall forthwith report the accident and the injury resulting therefrom to the employer, and any physician employed by the injured employee shall forthwith report the accident and the injury resulting therefrom to the employer, the insurance carrier and the commission.

F. When an accident occurs to an employee, the employer may designate in writing a physician chosen by the employer, who shall be permitted by the employee, or any person in charge of the employee, to make one examination of the injured employee in order to ascertain the character and extent of the injury occasioned by the accident. The physician so chosen shall forthwith report to the employer, the insurance carrier and the commission the character and extent of the injury as ascertained by him. If the accident is not reported by the employee or his physician forthwith, as required, or if the injured employee or those in charge of him refuse to permit the employer's physician to make the examination, and the injured employee is a party to the refusal, no compensation shall be paid for the injury claimed to have resulted from the accident. The commission may relieve the injured person or his dependents from the loss or forfeiture of compensation if it believes after investigation that the circumstances attending the failure on the part of the employee or his physician to report the accident and injury are such as to have excused them.

G. Within ten days after receiving notice of an accident, the employer shall inform his insurance carrier and the commission on such forms and in such manner as may be prescribed by the commission.

H. Immediately upon notice to the employer of an accident resulting in an injury to an employee, the employer shall provide the employee with the name and address of the employer's insurance carrier, the policy number and the expiration date.

I. Any person failing or refusing to comply with this section is guilty of a petty offense.

Sec. 2. Section 32-1963.01, Arizona Revised Statutes, is amended to read:

32-1963.01. Substitution for prescription drugs and biological products; requirements; label; definitions

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

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

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

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

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

D. 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", "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.

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

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

G. The liability of a pharmacist in substituting according to this section ~~shall be~~ IS no greater than that ~~which is~~ 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.

H. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic drug 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.

I. A PHARMACIST WHO FILLS A PRESCRIPTION ORDER FOR A SPECIFIC BIOLOGICAL PRODUCT THAT IS SUBJECT TO THE REQUIREMENTS OF 21 UNITED STATES CODE SECTION 353(b) MAY SUBSTITUTE A BIOSIMILAR PRODUCT FOR THE PRESCRIBED BIOLOGICAL PRODUCT IF ALL OF THE FOLLOWING CONDITIONS ARE MET:

1. THE FEDERAL FOOD AND DRUG ADMINISTRATION HAS DETERMINED THAT THE BIOSIMILAR PRODUCT IS INTERCHANGEABLE WITH THE PRESCRIBED BIOLOGICAL PRODUCT.

2. THE MEDICAL PRACTITIONER HAS NOT INDICATED, IN THE MANNER DESCRIBED IN SUBSECTION D OF THIS SECTION, THAT THE PHARMACIST MAY NOT SUBSTITUTE THE SPECIFIC BIOLOGICAL PRODUCT PRESCRIBED BY THE PRACTITIONER.

3. PHARMACY PERSONNEL HAVE NOTIFIED THE PATIENT OR PERSON PRESENTING THE PRESCRIPTION OF THE SUBSTITUTION OF THE INTERCHANGEABLE BIOSIMILAR PRODUCT IN WRITING AND ORALLY.

4. THE PHARMACIST NOTIFIES THE MEDICAL PRACTITIONER OF THE SUBSTITUTION IN WRITING OR ELECTRONICALLY WITHIN SEVENTY-TWO HOURS, INCLUDING THE NAME AND MANUFACTURER OF THE DISPENSED INTERCHANGEABLE BIOSIMILAR PRODUCT. THIS REQUIREMENT IS SATISFIED IF THE SUBSTITUTION INFORMATION IS

ENTERED INTO AN ELECTRONIC SYSTEM BETWEEN PRESCRIBING MEDICAL PRACTITIONERS AND PHARMACISTS, INCLUDING ELECTRONIC MEDICAL RECORDS.

5. THE PHARMACY RETAINS A WRITTEN OR ELECTRONIC RECORD OF THE SUBSTITUTION FOR AT LEAST SEVEN YEARS AFTER THE DATE OF THE SUBSTITUTION.

6. THE PHARMACIST PLACES ON THE CONTAINER THE NAME OF THE INTERCHANGEABLE BIOSIMILAR PRODUCT DISPENSED FOLLOWED BY THE WORDS "SUBSTITUTED FOR" FOLLOWED BY THE BRAND NAME OF THE BIOLOGICAL PRODUCT THAT IS BEING SUBSTITUTED. THE PHARMACIST SHALL INCLUDE ON THE FILE COPY OF THE PRESCRIPTION THE NAMES OF BOTH THE MANUFACTURER AND DISTRIBUTOR, IF APPLICABLE, OF THE INTERCHANGEABLE BIOSIMILAR PRODUCT DISPENSED IN LIEU OF THE PRESCRIBED BIOLOGICAL PRODUCT.

J. THE BOARD SHALL MAINTAIN ON ITS PUBLIC WEBSITE A CURRENT LIST OF INTERCHANGEABLE BIOSIMILAR PRODUCTS THAT MAY BE SUBSTITUTED FOR SPECIFIC BIOLOGICAL PRODUCTS.

~~I.~~ 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.

~~J.~~ L. The board by rule shall establish a list of drugs that shall not be used by dispensing pharmacists as generic equivalents for substitution.

~~K.~~ M. ~~In~~ FOR THE PURPOSES OF this section:

1. "BIOLOGICAL PRODUCT", "BIOSIMILAR PRODUCT" AND "INTERCHANGEABLE" IN REFERENCE TO A BIOLOGICAL PRODUCT HAVE THE SAME MEANINGS PRESCRIBED PURSUANT TO 42 UNITED STATES CODE SECTION 262.

~~1.~~ 2. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.

~~2.~~ 3. "Formulary" means a list of medicinal drugs.

~~3.~~ 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 federal 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.