1975 Assembly Bill 469 Date published: **March 19, 1976**

CHAPTER 168, Laws of 1975

AN ACT to repeal and recreate 450.02 (7); and to create 15.197 (15), 100.31, 140.90, 450.07 (4) (g), 450.075 and 450.077 of the statutes, relating to generic drug pricing and granting rule-making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. **Purpose.** The purpose of this act is to establish a state formulary of drug products and their equivalents for use by all prescribing practitioners and pharmacists in order that the citizens of this state may receive safe and clinically effective drug products at the most reasonable cost consistent with high quality; and to avoid confusion which may result from differing drug product nomenclature and from substantial price variations between clinically effective and chemically equivalent drug products.

SECTION 2. 15.197 (15) of the statutes is created to read:

15.197 (15) DRUG QUALITY COUNCIL. There is created in the department of health and social services a drug quality council consisting of 7 members appointed by the governor for staggered 3-year terms. Two members shall be physicians actively

practicing in this state, at least one of whom shall be selected from a list of nominees submitted by the president of the state medical society; 2 shall be pharmacists actively practicing in this state, at least one of whom shall be selected from a list of nominees submitted by the president of the Wisconsin pharmaceutical association; 2 shall be pharmacologists who are members of the faculties of accredited medical or pharmacy schools in this state; and one, who shall serve as chairman, shall represent the interests of the public and shall not be licensed as a physician or pharmacist, employ or be employed by any person licensed to practice medicine or pharmacy or have any pecuniary interest in the manufacturing, wholesaling or retailing of pharmaceutical products.

SECTION 3. 100.31 of the statutes is created to read:

100.31 Unfair discrimination in drug pricing. (1) DEFINITIONS. In this section:

(a) "Drug" means any substance subject to section 503 (f) of the federal food, drug and cosmetic act.

(b) "Seller" means any person who trades in drugs for resale to purchasers in this state.

(c) "Purchaser" means any person who engages primarily in selling drugs directly to consumers.

(2) PRICE DISCRIMINATION PROHIBITED. Every seller shall offer drugs from the formulary prepared by the department of health and social services under s. 140.90 (2) to every purchaser in this state, with all rights and privileges offered or accorded by such seller to his most favored purchaser, including purchase prices for similar volume purchases, rebates, free merchandise, samples and similar trade concessions. Nothing in this subsection shall prohibit the giving of a discount for volume purchases.

(3) TREBLE DAMAGES. Any purchaser damaged by violation of this section may bring an action against the seller to recover treble damages sustained by reason of such violation.

SECTION 4. 140.90 of the statutes is created to read:

140.90 Preparation and distribution of formulary of drug product equivalents.

(1) In this section:

(a) "Brand name" means the name, other than the generic name, that the labeler of a drug product places on its container at the time of packaging.

(b) "Drug product" means a specific drug in a specific dosage form from a known source of manufacture, whether by brand name or generic name.

(c) "Drug product equivalent" means a drug product containing active ingredients chemically identical to another drug product, which when administered by the same route of administration and in the same amount, has comparable safety and therapeutic effects.

(d) "Formulary" means a list of drug products prepared and published by the department in accordance with this section.

(e) "Generic name" means the official or established name given a drug product by the U.S. department of health, education and welfare or the U.S. adopted names council.

(f) "Hospital formulary system" means a method used by the medical staff of a hospital, working through a pharmacy and therapeutics committee, to evaluate and select from among numerous available medicinal agents those medicinal agents considered most useful therapeutically and to list dosage forms in which they may be most effectively administered.

(2) The department, with the advice of the drug quality council, shall prepare a formulary which lists commonly prescribed drug products by brand name together with their drug product equivalents ranked in the order of their average wholesale cost. In developing the formulary, the department may include any generic drug approved by the federal government under Titles 18 and 19 of the social security act or included in a formulary adopted by another governmental body or agency, except that whenever equivalency in therapeutic effect or bioavailability as related to toxic concentration and safety is critical for a class of drugs, a drug product equivalent in such a class shall be listed in the formulary only if there is evidence of its equivalency satisfactory to the department.

(3) The department shall distribute the formulary to all pharmacists and persons authorized to prescribe drugs and to other persons on request. The department shall review the formulary and make necessary revisions at least twice in each calendar year.

(4) Nothing in this section shall prohibit the establishment and operation of hospital formulary systems.

SECTION 5. 450.02 (7) of the statutes is repealed and recreated to read:

450.02 (7) (a) The examining board, upon notice and hearing, may suspend or revoke the registration of any person who is guilty of a felony or gross immorality, or who is addicted to alcoholic liquors or controlled substances to an extent affecting his fitness as a pharmacist, or who is otherwise unfit to practice as a pharmacist, or whose registration was secured by fraud or mistake or the giving of misinformation in any of the applications submitted to the examining board or who has been guilty of a violation of this chapter or ch. 161 or of violations of any of the rules of the examining board, or who has been guilty of acts of unprofessional conduct as defined in par. (b). No such revocation shall become effective until 20 days after notice of the decision of the examining board has been served upon the person accused. Decisions of the examining board under this section shall be subject to review as provided in ch. 227 and in case the provisions thereof are invoked by the accused within such 20-day period, such order of revocation shall become effective only at such time as may be ordered by the court.

(b) Unprofessional conduct means:

1. Sale of adulterated drugs.

2. Compounding, dispensing or selling, or causing or permitting the compounding, dispensing or sale of any drug which contains more or less than the proportionate quantity of ingredient or ingredients specified by the person ordering or prescribing such drug, or which contains an ingredient or ingredients other than those specified by the person ordering or prescribing such drug except prescriptions dispensed in accord with s. 450.075. Nothing in this subdivision shall be construed to prohibit the addition of such inert ingredients as emulsifiers, wetting agents, solvents, or like items as may be required in the art of compounding, preparing, mixing or otherwise producing drugs unless otherwise directed by the prescriber, or the operation of a hospital formulary system.

3. Violation of such standards as may from time to time be established or approved by the examining board.

4. Violation of s. 450.075.

SECTION 5m. 450.07 (4) (g) of the statutes is created to read:

450.07 (4) (g) The generic or common name by which the prescription drug is known, if any.

SECTION 6. 450.075 and 450.077 of the statutes are created to read:

450.075 Use of drug product equivalent in filling prescriptions. (1) DEFINITIONS. In this section:

(a) "Average wholesale cost" means the average wholesale cost as determined by the department under s. 140.90.

(b) "Drug product" has the meaning designated in s. 140.90 (1) (b).

(c) "Drug product equivalent" means a drug listed as a drug product equivalent in the formulary prepared under s. 140.90.

(d) "Formulary" has the meaning designated under s. 140.90 (1) (d).

(2) DRUG PRODUCT OR EQUIVALENT TO BE USED. Subject to sub. (3), a pharmacist shall fill every prescription with the drug product prescribed or its drug product equivalent, if such equivalent has an average wholesale cost, as established by the department, which is not greater than the drug product named in the prescription, and shall inform the consumer of the options available in filling the prescription. If a drug product listed in the formulary is prescribed generically, the prescription shall be filled with one of its drug product equivalents having a cost not higher than the average wholesale cost of all of its drug product equivalents. The pharmacist shall inform the consumer that the drug product with which the prescription is filled has a cost not higher than the average wholesale cost of all its drug product equivalents. The full difference in wholesale cost resulting from any substitution under this subsection shall be passed on to the consumer.

(3) EXCEPTION. If a prescriber indicates, by writing on the face of the prescription the phrase "No substitutions" or words of similar meaning or the initials "N.S.", that no drug product equivalent may be dispensed because only a specific brand of a drug can be tolerated by or is effective for a particular patient, sub. (2) does not apply. Such indication may not be made by means of a preprinted statement.

(4) REFILLING PRESCRIPTIONS. Prescriptions filled with a drug product equivalent may be refilled only with the same drug product used to fill the original prescription.

(5) POSTING REQUIRED. The most current edition of the formulary prepared by the department under s. 140.90 shall be conspicuously posted in every place where prescription drug products are sold in a manner prescribed by the department.

450.077 Labeling of drugs and drug products. Every drug or drug product delivered to any pharmacist, medical practitioner or hospital shall bear a label containing the generic name of the drug or drug product, its brand name if any, and the name and address of the distributor and the manufacturer of the drug or drug product.

SECTION 7. **Initial edition of formulary.** The first formulary shall be published no later than 6 months after the effective date of this act.

SECTION 8. **Effective date.** This act shall take effect on January 1, 1976.