750205-2

PHARMACISTS: Dispensing Generically Equivalent Drug Products.

PHYSICIANS: Prescribing Generically Equivalent Drug Products.

A physician may prevent the dispensing of a generically equivalent drug product by putting his handwritten statement: "Dispense as Written" or "D.A.W." on the prescription.

Absent a request by a purchaser, a pharmacist may not dispense a generically equivalent drug product unless the prescriber uses a preprinted prescription blank stating: "Another brand of a generically equivalent product, identical in dosage, form and content of active ingredients, may be dispensed"; and the prescriber does not write the initials "D.A.W." in a space or box adjacent to the statement.

A prescriber cannot direct that a prescription be dispensed as written by having prescription blanks preprinted in the following manner:

☐ Dispense as Written

☐ May Substitute Generically

Opinion No. 4839 February 5, 1975.

The Honorable Dale E. Kildee
The State Senate
State Capitol
Lansing, Michigan

and

Mr. Robert R. Eldredge
Executive Secretary
Board of Pharmacy
1033 South Washington Avenue
Lansing, Michigan

You have requested my opinion on two questions concerning 1974 PA 155, popularly referred to as the "Drug Substitution Bill," an amendment to the pharmacy act, 1962 PA 151; MCLA 338.1101 *et seq;* MSA 14.757(1) *et seq.* The first question requests clarification of the statutory provisions under which a prescriber may prevent dispensing of a generically equivalent drug product by a pharmacist. The second question asks whether a pharmacist may dispense a generically equivalent drug product in the absence of a request by the purchaser.

1962 PA 151, *supra,* was recently amended by 1974 PA 155. Previous to the amendment it was unlawful for a pharmacist to dispense, without the prescriber's authorization, a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed. However, 1974 PA 155 amends 1962 PA 151, *supra,* and, in certain circumstances, a pharmacist may dispense to a purchaser a generically equivalent drug product. This result is achieved through two specific statutory changes. First, the definition of "substitute" at 1962 PA 151, § 1(u); MCLA 338.1101; MSA 14.757(1), formerly included dispensing, without the prescriber's authorization, ". . . a different drug or brand of drug in place of the drug or

brand of drug ordered or prescribed." The act of substitution is punishable as a misdemeanor offense under 1962 PA 151, § 17(1); MCLA 338.1117; MSA 14.757(17). The amending act deletes from 1962 PA 151, § 1(u), *supra,* all reference to the phrase "or brand of drug," thereby permitting a pharmacist to dispense without the prescriber's authorization a generically equivalent drug product in place of the brand prescribed or ordered.

Second, having narrowed the definition of substitution, the legislature then described the circumstances in which a pharmacist may legally dispense a generically equivalent drug product in 1962 PA 151, § 14a; MCLA 338.1114a; MSA 14.757(14a), as follows:

> "(1) When a pharmacist receives a prescription for a brand name drug product, and the purchaser requests a lower cost generically equivalent drug product, the pharmacist may dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3). If a drug is dispensed which is not the prescribed brand, the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed, except as otherwise provided in section 14b.
>
> "(2) If a pharmacist dispenses a generically equivalent drug product, unless the prescription purchase is covered by a 'third party pay contract', the pharmacist shall pass on the savings in cost to the consumer. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products.
>
> "(3) The pharmacist shall not dispense a generically equivalent drug product under subsection (1) of this section if
>
> "(a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his own handwriting 'dispense as written' or 'D.A.W.' on the prescription, or
>
> "(b) The prescriber, having preprinted on his prescription blanks the statement 'another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed D.A.W.' writes the initials 'D.A.W.' in a space, box or square adjacent to such statement, or
>
> "(c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated.
>
> "(4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser." MCLA 338.1114a; MSA 14.757(14a)

As to the first question, you have asked whether the prescriber can direct that a prescription be dispensed as written by having prescription blanks preprinted in the following manner:

☐ Dispense as Written
☐ May Substitute Generically

According to your question, the prescriber would then check the appropriate box and place his initials beside the box.

1962 PA 151, § 14a(3), *supra,* sets forth three procedures to be followed if the prescriber desires to prevent the dispensing of a generically equivalent drug product. First, the prescriber may write in his own handwriting the words, "dispense as written" or the initials "D.A.W." on the prescription. Second, if the prescription blanks have the specific preprinted statement: "Another brand of a generically equivalent drug product identical in dosage, form and content of active ingredients may be dispensed unless initialed D.A.W.," then the prescriber may place the initials "D.A.W." in a square or box adjacent to the statement. Third, in the case of a prescription by any means other than in writing, the prescriber may expressly indicate that the prescription is to be dispensed as communicated.

By the terms of the statute, a pharmacist is prohibited from dispensing a generically equivalent drug product only in the three situations described above. Moreover, the statute makes no allowance for any other method by which the prescriber can insure that the prescription will be dispensed as written. Therefore, since the method that you propose is not in conformance with the statutorily recognized methods, in my opinion, a pharmacist would not be prevented from dispensing a generically equivalent drug product.

The second question requests my opinion as to whether a pharmacist may dispense a generically equivalent drug product in the absence of a request by the purchaser. 1962 PA 151, § 14a, *supra,* sets forth simply and succinctly the circumstances in which a pharmacist may dispense a generically equivalent drug product.

1962 PA 151, § 14a, *supra,* defines the circumstances in which a patient may obtain and a pharmacist may dispense a generically equivalent drug product. Subject to the sole exception contained in 1962 PA 151, § 14a(3)(b), *supra,* as explained below, 1962 PA 151, § 14a(1), *supra,* set forth four conditions which must be met before a pharmacist may dispense a generically equivalent drug product. First, the purchaser must have a prescription which indicates a brand name drug product as being prescribed. Second, the purchaser must request that a lower cost generically equivalent drug be dispensed. Third, the generically equivalent drug product must in fact have a lower total charge than the drug product originally prescribed, subject to the exceptions set forth in 1962 PA 151, § 14a(4), *supra,* which allows the dispensing of a higher cost generically equivalent drug product if the purchaser agrees to pay the higher total charge. Fourth and finally, the prescriber must not have exercised the power granted under 1962 PA 151, § 14a(3), *supra,* to mandate that the prescription be dispensed as written.

However, each of the four conditions need not be present where, as provided in 1962 PA 151, § 14a(3)(b), *supra,* the prescriber has a preprinted prescription blank which states: "Another brand of generically equivalent drug product identical in dosage, form and content of active ingredients may be dispensed unless initialed "D.A.W." In this situation, no request by the purchaser would be deemed necessary. In effect, the

preprinted statement directly authorizes the pharmacist to dispense a generically equivalent drug product and, thus, the pharmacist needs no request by the purchaser. While the dispensing of a generically equivalent drug product in response to a preprinted prescription form is not subject to the lower cost guarantee found in 1962 PA 151, § 14a(1), *supra,* the total charge of the drug product still may not exceed the total charge of the drug originally prescribed as provided in 1962 PA 151, § 14a(4), *supra.*

Deviation from the express provisions of 1962 PA 151, § 14a, *supra,* could result in both criminal and licensure action brought against the offending pharmacist. The pharmacist may be prosecuted criminally under 1962 PA 151, § 23(2); MCLA 338.1123; MSA 14.757(23), which states as follows:

> "A person who violates sections 14a, . . . is guilty of a misdemeanor and shall be fined not less than $100.00 nor more than $500.00." MCLA 338.1123; MSA 14.757(23)

Moreover, the pharmacist is subject to possible action pursuant to 1962 PA 151, § 15(7); MCLA 338.1115; MSA 14.757(15), which states that the Board shall have the power to revoke or suspend the license of any person who shall have violated any of the provisions of this act or any other acts enforced by this Board or any rules adopted by the Board.

Therefore, in my opinion, the response to your first question is that the prescriber must follow one of the three specific statutory methods found in 1962 PA 151, § 14a(3), *supra,* to prevent a pharmacist from dispensing a generically equivalent drug product. As to your second question, unless the prescriber has the preprinted statement on the prescription blank: "Another brand of generically equivalent drug product identical in dosage, form and content of active ingredients may be dispensed unless initialed "D.A.W.," a pharmacist may not dispense a generically equivalent drug product absent a request from the purchaser.

FRANK J. KELLEY,
Attorney General.