

AN ACT

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To amend the District of Columbia Prescription Drug Pricing Information Act to establish the Orange Book as the generic formulary for the District of Columbia, to authorize the Boards of Medicine and Pharmacy to create a therapeutic interchange list, to update protocols regarding the dispensing of substitute drug products, to require notification of drug substitutions, and to include new definitions.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the “Prescription Drug Dispensing Practices Reform Act of 2009”.

Sec. 2. The District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*), is amended as follows:

(a) Section 301 (D.C. Official Code § 48-803.01) is amended to read as follows:

“Sec. 301. Generically equivalent drug formulary; therapeutic interchange list.

“(a) The formulary of generically equivalent drug products for the District of Columbia shall be the chemical and generic drugs contained in the Food and Drug Administration publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” including all updates issued by the Food and Drug Administration (“Orange Book”).

“(b) The Boards of Pharmacy and Medicine may jointly establish a therapeutic interchange list.

“(c) If a therapeutic interchange list is established pursuant to subsection (b) of this section:

“(1) The Boards of Pharmacy and Medicine shall:

“(A) Revise or supplement the therapeutic interchange list as necessary;

“(B) Establish procedures to allow a prescriber to consent to the substitution of therapeutically equivalent drug products without prior approval based on the therapeutic interchange list; provided, that a prescriber be allowed to limit authorization to specific conditions or patients and that no prescriber be required for any reason to consent to

participation in the therapeutic interchange list; and

“(C) Establish and maintain a database, searchable in real time, of those prescribers who have consented to use of the therapeutic interchange list, including any restrictions based on specific conditions or patients; and

“(2) The Department of Health shall distribute the therapeutic interchange list to all pharmacies licensed in the District and shall publish it regularly in the District of Columbia Register.”.

(b) Section 302 (D.C. Official Code § 48-803.02) is amended as follows:

(1) The section heading is amended to read as follows:

“Sec. 302. Dispensing of generically equivalent drug products.”.

(2) Subsection (a) is amended to read as follows:

“(a)(1) When a pharmacist receives a prescription for a brand name drug, the pharmacist may dispense a generically equivalent drug product that is listed in the Orange Book; provided, that the pharmacist shall dispense a generically equivalent drug product if requested by the purchaser, except as provided in section 303.

“(2) If a generic substitution is made pursuant to this subsection, the pharmacist shall dispense the generically equivalent drug product in stock having the lowest cost to the person purchasing the drug product.”.

(3) Subsection (b) is amended by striking the phrase “having the lowest current selling price” and inserting the phrase “that has the lowest cost to the person purchasing the drug product” in its place.

(4) Subsection (c) is repealed.

(c) Section 303 (D.C. Official Code § 48-803.03) is amended to read as follows:

“Sec. 303. Dispensing of substitute drug products - conditions.

“A pharmacist shall not dispense a:

“(1) Substitute drug product if the person purchasing the drug product or the patient for whom it is intended indicates a preference for the drug product actually prescribed;

“(2) Generically equivalent drug product pursuant to section 302 if:

“(A) The prescriber writes on a prescription order, signed by the prescriber, in the prescriber's own handwriting "dispense as written" or "D.A.W." or a similar notation; provided, that checking or initialing a box preprinted or stamped on a prescription form shall not constitute an acceptable notation; or

“(B) The prescriber, by telephone, expressly indicates that the prescription is to be dispensed as communicated and this indication is noted in the pharmacist's own handwriting in the manner provided in subparagraph (A) of this paragraph;

“(3)(A) Therapeutically equivalent drug product unless:

“(i)(I) The pharmacist or pharmacist's agent obtains prior approval from the prescriber or the prescriber's agent before the therapeutically equivalent drug product can be dispensed; or

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“(II) The therapeutically equivalent drug product is included on the therapeutic interchange list and the endorsing prescriber has given consent to the Boards of Pharmacy and Medicine to permit therapeutic interchange without prior approval;

“(ii) The person purchasing the drug product provides consent to the therapeutic interchange;

“(iii) The therapeutically equivalent drug product does not have a higher cost to the purchaser than the originally prescribed drug product; provided, that the pharmacist may dispense a more expensive therapeutically equivalent drug product if consent is provided by the purchaser; and

“(iv) The dispensing pharmacist, or pharmacist’s agent, has notified the prescriber or prescriber’s agent of the specific drug and dose dispensed.

“(B) A pharmacist shall not dispense a therapeutically equivalent drug product for a prescription refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug but shall dispense the drug as prescribed.”.

(d) A new section 303a is added to read as follows:

“Sec. 303a. Dispensing of substitute drug products by pharmacists - notification of substitution.

“(a) An individual shall be notified of a drug substitution and provided the right to refuse the substitution prior to purchase of the substitute drug product.

“(b)(1) The Department of Health shall create and distribute to all pharmacies signs that state in block letters not less than one inch in height: “This pharmacy may substitute a less expensive drug product that is equivalent to the one prescribed by your health care practitioner unless you request otherwise.”

“(2) Each pharmacy shall display the sign in a prominent place that has a clear and unobstructed public view at or near the place where prescriptions are dispensed.”.

(e) Section 304 (D.C. Official Code § 48-803.04) is amended by striking the phrase “section 302” and inserting the phrase “this title” in its place.

(f) Section 305 (D.C. Official Code § 48-803.05) is amended as follows:

(1) Subsection (a) is amended to read as follows:

“(a) The substitution of drugs by a licensed pharmacist under this title shall not constitute the practice of medicine. Nothing in this title shall be construed as authorizing a pharmacist to prescribe any drug or medication.”.

(2) Subsection (b) is amended by striking the phrase “therapeutically equivalent” and inserting the phrase “generically equivalent drug products” in its place.

(g) Section 2 (D.C. Official Code § 48-804.51) is amended to read as follows:

“Sec. 2. Definitions.

“For the purposes of this act, the term:

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(1) “Agent” means an individual who:

“(A) Is under the immediate and personal supervision of a prescriber or pharmacist and has written authorization, which shall be available for review upon request, to act on behalf of or at the direction of the prescriber or pharmacist when seeking or obtaining approval of a therapeutic interchange; or

“(B) If not under the immediate and personal supervision of a prescriber or pharmacist, holds a license to administer drugs, such as a nurse, physician’s assistant, or other pharmacist.

“(2) “Endorsing prescriber” means a prescriber who has reviewed the therapeutic interchange list and has notified the Boards of Pharmacy and Medicine in writing that he or she has agreed to allow the therapeutic interchange.

“(3) “Issue date” means the 1st day of the 4th full calendar month after April 7, 1977, and the day following the end of each year after the 1st such issue date.

“(4) “Most commonly used prescription drugs” means the prescription drug products that were most frequently paid for by the Medicaid program operated by the District of Columbia government under a state plan filed in accordance with section 1902 of the Social Security Act (§ 1396a of Title 42, United States Code), in the 3 consecutive months ending 60 days before an issue date.

“(5) “Person” means any individual, partnership, corporation, organization, or association.

“(6) “Pharmacy” means a pharmacy that provides services to the public on an outpatient basis.

“(7) “Prescriber” means a person who is licensed, registered, or otherwise authorized by the District to prescribe and administer prescription drugs for human use in the course of a professional practice.

“(8) “Substitute drug product” means a drug product different than the one originally prescribed by a prescriber.

“(9) “Therapeutic interchange” means the dispensing of chemically dissimilar but therapeutically equivalent drug products.

“(10) “Therapeutic interchange list” means a list of therapeutically equivalent drug products.

“(11) “Therapeutically equivalent drug product” means a drug product that is chemically dissimilar but produces essentially the same therapeutic outcome.”.

Sec. 3. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

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Sec. 4. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of Congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.

Chairman
Council of the District of Columbia

Mayor
District of Columbia