

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 130
(A-19)

Introduced by: Texas

Subject: Notification of Generic Drug Manufacturing Changes

Referred to: Reference Committee A
(John Montgomery, MD, Chair)

- 1 Whereas, Generic drug use is prevalent across the medical spectrum, with multiple
2 manufacturers producing the same base drug; and
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4 Whereas, Pharmacies and pharmacy benefit managers may change a drug prescription from
5 one generic drug manufacturer to another; and
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7 Whereas, Generic drugs are not required to replicate the extensive clinical trials used in the
8 development of brand drugs; and
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10 Whereas, Bioequivalence only needs 24 to 36 healthy, normal volunteers to demonstrate the
11 time it takes a generic to reach the bloodstream and its concentration in the bloodstream; and
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13 Whereas, Two versions of a drug are said to be bioequivalent if the 90% confidence intervals for
14 the ratios of the geometric means of the area under the curve and chemical makeup fall within
15 80% and 125%; and
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17 Whereas, Generic drugs are not required to contain the same nonmedicinal ingredients as the
18 brand name drug or another manufacturer's generic drug; and
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20 Whereas, Most patients are unaware of a change from one manufacturer to another of their
21 generic drug prescription; and
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23 Whereas, The unknown change in generic manufacturers has caused harm to patients;
24 therefore be it
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26 RESOLVED, That our American Medical Association lobby Congress to pass legislation that
27 ensures that each patient is expressly notified at the time of dispensing by the pharmacy or
28 pharmacy benefit manager of a change in the manufacturer of his or her generic medication.
29 (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 05/24/19

RELEVANT AMA POLICY

Prescription Labeling H-115.974

Our AMA recommends (1) That when a physician desires to prescribe a brand name drug product, he or she do so by designating the brand name drug product and the phrase "Do Not Substitute" (or comparable phrase or designation, as required by state law or regulation) on the prescription; and when a physician desires to prescribe a generic drug product, he or she do so by designating the USAN-assigned generic name of the drug on the prescription.

(2) That, except where the prescribing physician has indicated otherwise, the pharmacist should include the following information on the label affixed to the container in which a prescription drug is dispensed: in the absence of product substitution, (a) the brand and generic name of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; and (d) the name of the manufacturer or distributor.

(3) When generic substitution occurs: (a) the generic name (or, when applicable, the brand name of the generic substitute ["branded" generic name]) of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; (d) the manufacturer or distributor; and (e) either the phrase "generic for [brand name prescribed]" or the phrase "substituted for [brand name prescribed]".

(4) When a prescription for a generic drug product is refilled (e.g., for a patient with a chronic disease), changing the manufacturer or distributor should be discouraged to avoid confusion for the patient; when this is not possible, the dispensing pharmacist should satisfy the following conditions: (a) orally explain to the patient that the generic drug product being dispensed is from a different manufacturer or distributor and, if possible (e.g., for solid oral dosage forms), visually show the product being dispensed to the patient; (b) replace the name of the prior generic drug manufacturer or distributor on the label affixed to the prescription drug container with the name of the new generic drug manufacturer or distributor and, show this to the patient; (c) affix to the primary label an auxiliary (sticker) label that states, "This is the same medication you have been getting. Color, size, or shape may appear different;" and (d) place a notation on the prescription record that contains the name of the new generic drug manufacturer or distributor and the date the product was dispensed.

Citation: BOT Rep. 1, A-95; Amended: CSA Rep. 2, I-99; Modified Res. 512, I-00; Reaffirmed: CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmed: Sub. Res. 509, A-07; Reaffirmed: CSAPH Rep. 01, A-17

Pharmaceutical Benefits Management Companies H-125.986

Our AMA:

(1) encourages physicians to report to the Food and Drug Administrations (FDA) MedWatch reporting program any instances of adverse consequences (including therapeutic failures and adverse drug reactions) that have resulted from the switching of therapeutic alternates;

(2) encourages the Federal Trade Commission (FTC) and the FDA to continue monitoring the relationships between pharmaceutical manufacturers and PBMs, especially with regard to manufacturers' influences on PBM drug formularies and drug product switching programs, and to take enforcement actions as appropriate;

(3) pursues congressional action to end the inappropriate and unethical use of confidential patient information by pharmacy benefits management companies;

(4) states that certain actions/activities by pharmacy benefit managers and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients;

(5) encourages physicians to routinely review their patient's treatment regimens for appropriateness to ensure that they are based on sound science and represent safe and cost-effective medical care;

(6) supports efforts to ensure that reimbursement policies established by PBMs are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medications; and

(7) encourages the FTC and FDA to monitor PBMs policies for potential conflicts of interests and anti-trust violations, and to take appropriate enforcement actions should those policies advantage pharmacies in which the PBM holds an economic interest.

Citation: BOT Rep. 9, I-97; Appended: Res. 224, I-98; Appended: Res. 529, A-02; Reaffirmed: Res. 533; A-03; Reaffirmation I-08; Reaffirmation A-10; Reaffirmed: Alt. Res. 806, I-17; Modified: Res. 242, A-18