

111TH CONGRESS
2^D SESSION

H. R. 6255

To require mail-order pharmacies to notify customers when generic drugs become available and to prevent mail-order pharmacies from substituting drugs without the express authorization of the prescriber.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2010

Ms. SHEA-PORTER introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require mail-order pharmacies to notify customers when generic drugs become available and to prevent mail-order pharmacies from substituting drugs without the express authorization of the prescriber.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. NOTIFICATION OF GENERIC DRUG AVAIL-**
4 **ABILITY AND REQUIREMENT OF AUTHORIZA-**
5 **TION FOR DRUG SUBSTITUTIONS.**

6 (a) NOTIFICATION.—If a generic drug that is the
7 pharmaceutical equivalent of a brand name drug becomes
8 available, a mail-order pharmacy shall inform all cus-

1 tomers for whom it receives prescriptions to dispense such
2 brand name drug, that such a generic drug is available.

3 (b) AUTHORIZED SUBSTITUTION ONLY.—

4 (1) MAIL-ORDER PHARMACY REQUIREMENTS.—

5 A mail-order pharmacy may only dispense a generic
6 drug in substitution for brand name drug (or a
7 brand name drug in substitution for a generic drug)
8 if the mail-order pharmacy—

9 (A) notifies the customer that the phar-
10 macy will request that the prescriber provide an
11 authorization to make such a substitution; and

12 (B) after providing such notification, ob-
13 tains the express written authorization of the
14 prescriber of the drug to make such a substi-
15 tution.

16 (2) PRESCRIBER REQUIREMENTS.—If a pre-
17 scriber provides an authorization under paragraph
18 (1)(B) to a mail-order pharmacy, the prescriber
19 shall provide notice to the customer of such action.

20 (c) CIVIL MONETARY PENALTIES.—

21 (1) IN GENERAL.—The Secretary of Health and
22 Human Services may assess a civil monetary penalty
23 against a mail-order pharmacy in an amount not to
24 exceed \$500 for each violation, by such pharmacy, of
25 the requirements of—

1 (A) subsection (a) (relating to notice to
2 customers); or

3 (B) subsection (b)(1) (relating to obtaining
4 authorization from prescribers before making
5 drug substitutions).

6 (2) PROCEDURE AND JUDICIAL REVIEW.—Sub-
7 sections (b), (c), and (d) of section 307 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 335b) apply to a civil monetary penalty under para-
10 graph (1) in the same manner that such subsections
11 apply to civil penalties under subsection (a) of such
12 section 307.

13 (d) DEFINITIONS.—For purposes of this section:

14 (1) BRAND NAME DRUG.—The term “brand
15 name drug” means a prescription drug for which an
16 application is approved under section 505(c) of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 355(c)), including an application referred to in sec-
19 tion 505(b)(2) of such Act.

20 (2) GENERIC DRUG.—The term “generic drug”
21 means a prescription drug that—

22 (A) has lost the patent protection that is
23 provided to a single manufacturer or multiple
24 manufacturers; and

1 (B) is widely available from multiple man-
2 ufacturers.

3 (3) MAIL-ORDER PHARMACY.—The term “mail-
4 order pharmacy” means a pharmacy that—

5 (A) is State-licensed; and

6 (B) conducts its pharmaceutical business
7 primarily through mail services.

8 (e) PREEMPTION.—This section preempts the laws of
9 any State to the extent that such State laws are incon-
10 sistent with this section.

11 (f) EFFECTIVE DATE.—This section shall take effect
12 on January 1, 2011.

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