

107TH CONGRESS
1ST SESSION

H. R. 2740

To amend the Federal Food, Drug, and Cosmetic Act with respect to the receipt of donated prescription drug samples by charitable health care entities.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2001

Mr. BURR of North Carolina (for himself and Mr. KLECZKA) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the receipt of donated prescription drug samples by charitable health care entities.

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. SHORT TITLE.**

4 This Act may be cited as the “Drug Access Act of
5 2001”.

6 **SEC. 2. DONATION OF PRESCRIPTION DRUG SAMPLES TO**
7 **CHARITABLE HEALTH CARE ENTITIES.**

8 Section 503(d) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 353(d)) is amended—

1 (1) in paragraph (1), in the matter preceding
2 subparagraph (A), by striking “paragraphs (2) and
3 (3)” and inserting “paragraphs (2) through (4)”;
4 and

5 (2) by adding at the end the following para-
6 graph:

7 “(4)(A) A charitable health care entity may receive
8 a drug sample donated by a person described in subpara-
9 graph (A), (B), or (C) of paragraph (1) or by another
10 charitable health care entity for dispensing to a patient
11 of the charitable institution, and a charitable health care
12 entity may donate a drug sample to another charitable
13 health care entity for dispensing to its patients, if the fol-
14 lowing requirements are met:

15 “(i) Delivery of the donated drug sample to the
16 charitable health care entity is completed by mail or
17 common carrier, collection by an authorized agent or
18 employee of the recipient charitable health care enti-
19 ty, or personal delivery by a licensed practitioner or
20 an agent or employee of the donating charitable
21 health care entity.

22 “(ii) The charitable health care entity receiving
23 the donated drug sample executes a written receipt
24 for the drug sample upon its delivery and provides
25 for the return of the receipt to the donating entity.

1 “(iii) The donated drug sample received by the
2 charitable health care entity is in its original, un-
3 opened packaging with its labeling intact.

4 “(iv) Before dispensing such sample to a pa-
5 tient, the sample is examined by a licensed practi-
6 tioner or registered pharmacist to confirm that the
7 sample is not adulterated or misbranded.

8 “(B) For purposes of this subsection, the term ‘chari-
9 table health care entity’ means an entity that provides di-
10 agnostic, medical, surgical, or dental treatment or provides
11 chronic or rehabilitative care; is described in section
12 501(e)(3) of the Internal Revenue Code of 1986; and is
13 under section 501(a) of such Code exempt from tax-
14 ation.”.

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