

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4673

To amend the Public Health Service Act to provide for voluntary reporting by health care providers of medication error information in order to assist appropriate public and nonprofit private entities in developing and disseminating recommendations and information with respect to preventing medication errors.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2002

Mrs. MORELLA introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to provide for voluntary reporting by health care providers of medication error information in order to assist appropriate public and nonprofit private entities in developing and disseminating recommendations and information with respect to preventing medication errors.

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 “Medication Error Pre-  
5       vention Act of 2002”.

1 **SEC. 2. VOLUNTARY REPORTING PROGRAM REGARDING**  
2 **MEDICATION ERRORS; DEVELOPMENT AND**  
3 **DISSEMINATION OF RECOMMENDATIONS FOR**  
4 **PREVENTING MEDICATION ERRORS.**

5 Part B of title II of the Public Health Service Act  
6 (42 U.S.C. 238 et seq.) is amended by adding at the end  
7 the following section:

8 **“SEC. 249. VOLUNTARY REPORTING PROGRAM REGARDING**  
9 **MEDICATION ERRORS; DEVELOPMENT AND**  
10 **DISSEMINATION OF RECOMMENDATIONS FOR**  
11 **PREVENTING MEDICATION ERRORS.**

12 “(a) PRIVILEGED LEGAL STATUS OF REPORTED IN-  
13 FORMATION.—If the Secretary approves a program as  
14 meeting the criteria described in subsection (b) to serve  
15 as the reporting program for purposes of this section, any  
16 medication error information submitted to the reporting  
17 program by a health care provider pursuant to an agree-  
18 ment under paragraph (3) of such subsection is privileged  
19 for purposes of Federal and State judicial proceedings in  
20 civil matters, and for purposes of Federal and State ad-  
21 ministrative proceedings, including with respect to dis-  
22 covery and subpoenas.

23 “(b) CRITERIA FOR REPORTING PROGRAM.—With re-  
24 spect to the approval by the Secretary of a reporting pro-  
25 gram for purposes of this section, the criteria referred to  
26 in subsection (a) are as follows:

1           “(1) The reporting program is operated by The  
2           United States Pharmacopeial Convention, Incorporated (except that if such entity declines to operate a reporting program for purposes of this section,  
3           the Secretary may accept another nonprofit private  
4           entity for such purposes).  
5

6           “(2) Under such program, health care providers  
7           voluntarily submit medication error information to  
8           the program, and the program uses the information  
9           for the purpose of developing and disseminating recommendations and information with respect to preventing such errors, including recommendations in  
10          the form of protocols, procedures, and best-practices  
11          information.  
12

13          “(3) The use by the program of medication  
14          error information submitted to the program by a  
15          health care provider is governed by an agreement  
16          entered into by the program and the provider.  
17

18          “(4) Such agreement includes the following  
19          policies (without regard to whether the following language is used in the agreement):  
20

21                 “(A) Subject to subparagraph (B), the reporting program reserves the right to disclose  
22                 to third parties medication error information  
23                 submitted by a health care provider if, in the  
24  
25

1 judgment of the program, the information can  
2 be used for purposes of furthering research,  
3 education, standards setting, improvement in  
4 processes, product improvement, public health,  
5 or public safety.

6 “(B) If such a disclosure is made, the ex-  
7 tent of information disclosed will be limited to  
8 the information required to meet the purposes  
9 described in subparagraph (A).

10 “(c) FEDERAL DISCLOSURES.—Officers and employ-  
11 ees of a Federal agency may not disclose any medication  
12 error information that is received by the agency from the  
13 reporting program pursuant to an agreement between the  
14 agency and the program, except to the extent that disclo-  
15 sure of the information is authorized by the agreement.  
16 The preceding sentence applies notwithstanding any other  
17 provision of law.

18 “(d) SCOPE OF PRIVILEGE.—With respect to Federal  
19 and State judicial proceedings in civil matters, and Fed-  
20 eral and State administrative proceedings:

21 “(1) In the case of a health care provider:

22 “(A) The privilege under subsection (a)  
23 protects all medication error information of the  
24 provider that is provided in a submission to the  
25 reporting program or is developed for purposes

1 of such a submission, subject to subparagraph  
2 (B).

3 “(B) The privilege does not protect medi-  
4 cation error information in patient medical  
5 records of the provider, or other information  
6 that is in the custody of the provider and is de-  
7 veloped or maintained by the provider sepa-  
8 rately from the process of developing medica-  
9 tion error information for submission to the  
10 program.

11 “(2) In the case of the reporting program, the  
12 privilege protects all medication error information  
13 that is received by the program pursuant to agree-  
14 ments under subsection (b)(3).

15 “(3) In the case of other entities (whether pub-  
16 lic or private), the privilege protects all medication  
17 error information that is received by the entity from  
18 the reporting program pursuant to an agreement be-  
19 tween the entity and the program, except to the ex-  
20 tent that disclosure of the information is authorized  
21 by the agreement.

22 “(e) RULE OF CONSTRUCTION.—The submission by  
23 a health care provider of medication error information to  
24 the reporting program may not be construed as waiving

1 any privilege that, under Federal or State constitutions  
2 or laws, may exist with respect to the information.

3 “(f) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘health care provider’ means in-  
5 dividuals and organizations that provide health serv-  
6 ices. Such term includes—

7 “(A) physicians, nurses, pharmacists, and  
8 other health professionals; and

9 “(B) hospitals, pharmacies, clinics, long-  
10 term care facilities, intermediate care facilities,  
11 residential treatment centers, and other entities  
12 that provide health services.

13 “(2) The term ‘medication error’ means any  
14 preventable event that may cause or lead to inappro-  
15 priate medication use or patient harm while the  
16 medication is in the control of the health care pro-  
17 fessional, patient, or consumer. Such events may be  
18 related to professional practice, health care products,  
19 procedures, and systems, including prescribing;  
20 order communication; product labeling, packaging,  
21 and nomenclature; compounding; dispensing; dis-  
22 tribution; administration; education; monitoring; and  
23 use.

24 “(3) The term ‘medication error information’  
25 means information developed by or on behalf of a

1 health care provider in connection with a medication  
2 error.

3 “(4) The term ‘reporting program’ means the  
4 program approved under subsection (a).”

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