

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3632

To require the mandatory reporting of deaths resulting from errors in the prescribing, dispensing, and administration of drugs, to allow the continuation of voluntary reporting programs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 22, 1993

Mr. COYNE (for himself and Mr. STARK) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Ways and Means

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## A BILL

To require the mandatory reporting of deaths resulting from errors in the prescribing, dispensing, and administration of drugs, to allow the continuation of voluntary reporting programs, and for other purposes.

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 AND PURPOSE**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Safe Medications Act of 1993”.

6 (b) PURPOSE.—It is the purpose of this Act to have  
7 the Secretary of Health and Human Services create a data  
8 bank for reports of errors in the prescribing, dispensing,

1 and administration of drugs, to establish a program using  
2 such data to assist in preventing such errors, and to edu-  
3 cate and inform health care professionals of the deaths  
4 that may occur in the course of drug therapy.

5 **SEC. 2. REPORTING.**

6 (a) IN GENERAL.—Any pharmacy, hospital, long-  
7 term care facility, physician’s office, or other health care  
8 facility, as defined by the Secretary of Health and Human  
9 Services by regulation, in which an error occurs in the pre-  
10 scribing, dispensing, or administration of a drug to an in-  
11 dividual which results in the individual’s death shall report  
12 such error and resulting death to the Secretary of Health  
13 and Human Services under section 3. Such a report shall  
14 be made not later than 10 working days after the date  
15 of the discovery of the error resulting in such death.

16 (b) REPORT REQUIREMENTS.—Each report of an  
17 error in the prescribing, dispensing, or administration of  
18 a drug to an individual shall contain—

19 (1) an identification of the person making the  
20 report, including the address and telephone number  
21 of such person, and the name and address of the fa-  
22 cility in which the error occurred,

23 (2) the brand names of the drugs involved, the  
24 generic names of the drugs, the manufacturers of  
25 the drugs, the labeler of the drug if different from

1 the manufacturer, the dosage form of the drugs, the  
2 strength of the drugs, and the type and size of the  
3 containers,

4 (3) the lot number of the drugs, if available,

5 (4) a description of the error,

6 (5) information on the patient for whom the  
7 drug was prescribed, dispensed, or administered, in-  
8 cluding the patient's age and sex,

9 (6) the diagnosis for which the drug was pre-  
10 scribed, dispensed, or administered,

11 (7) the date and time the death, and

12 (8) when and how the error was discovered.

13 **SEC. 3. DATA BANK.**

14 (a) ESTABLISHMENT.—The Secretary of Health and  
15 Human Services, acting through the Commissioner of  
16 Food and Drugs, shall establish a data bank to receive  
17 reports under section 2 of errors resulting in deaths.

18 (b) SECRETARIAL ACTION.— The Secretary shall re-  
19 view information reported to the data bank on an ongoing  
20 basis to determine trends relating to drugs and shall re-  
21 port such information to the compilers of the official com-  
22 pendia on an ongoing basis for consideration of revision  
23 of the packaging and labeling requirements or other stand-  
24 ards for drugs for dissemination of information to physi-  
25 cians, pharmacists, and other health professionals involved

1 in the prescribing, dispensing, and administration of drugs  
2 to patients. Such reporting of aggregate data shall be done  
3 in a manner which assists such health professionals in  
4 identifying and reducing patterns and incidents of inap-  
5 propriate and misuse associated with certain drugs.

6 (c) CONFIDENTIALITY.— The identity of a person  
7 making a report to the data bank, the deceased, or the  
8 individual believed to have caused the error shall be con-  
9 sidered as privileged and confidential information for pur-  
10 poses of any law requiring disclosure of information.

11 (d) SHARED INFORMATION.—The Secretary shall  
12 share the reported information with licensing, accredita-  
13 tion, and inspection organizations for their followup with  
14 the appropriate organization to ensure that there has not  
15 been underreporting of medication errors related to  
16 deaths.

17 (e) ENFORCEMENT.—Whoever with false pretenses  
18 reports to the data bank, requests information from the  
19 data bank, or unlawfully gains access to the data bank  
20 shall be fined not more than \$15,000 or imprisoned for  
21 not more than 3 years, or both, except that if a person  
22 commits a violation of this subsection after a conviction  
23 for a violation of this subsection has become final, such  
24 person shall be fined not more than \$25,000 or imprisoned  
25 for not more than 3 years, or both.

1 **SEC. 4. PENALTIES.**

2 (a) IMPOSITION OF FINE.—Any institution that does  
3 not make a report as required by section 2 shall be subject  
4 to a fine of \$15,000 for each report not made. Within 60  
5 days of a conviction under this subsection, a person shall  
6 submit to the Secretary of Health and Human Services  
7 a plan for the reporting to the data bank of drug prescrib-  
8 ing, dispensing, and administration errors.

9 (b) MANDATORY EXCLUSION FROM MEDICARE AND  
10 STATE HEALTH CARE PROGRAMS.—Section 1128(a) of  
11 the Social Security Act (42 U.S.C. 1320a–7(a)) is amend-  
12 ed by adding at the end the following new paragraph:

13 “(3) FAILURE TO REPORT DEATHS RESULTING  
14 FROM ERRORS IN THE PRESCRIBING, DISPENSING,  
15 AND ADMINISTRATION OF DRUGS.—Any individual  
16 or entity that has failed to meet the requirements of  
17 section 2 of the Safe Medications Act of 1993.”.

18 **SEC. 5. AUTHORIZATION.**

19 There are authorized to be appropriated to carry out  
20 this Act and the amendment made by this Act such sums  
21 as may be necessary.

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