

108TH CONGRESS
1ST SESSION

H. R. 3015

To amend the Public Health Service Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 4, 2003

Mr. WHITFIELD (for himself and Mr. PALLONE) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, 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.**

4 This Act may be cited as the “National All Schedules
5 Prescription Electronic Reporting Act of 2003”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) The Harold Rogers Prescription Monitoring
2 Program has supplied and will continue to supply
3 critically important information and experience re-
4 garding effective prescription drug monitoring prac-
5 tices.

6 (2) Schedule II, III, and IV controlled sub-
7 stances have a useful and legitimate medical purpose
8 and are necessary to maintain the health and gen-
9 eral welfare of the American people.

10 (3) Schedule II, III, and IV controlled sub-
11 stances have a moderate to high potential for misuse
12 when the prescribing practitioner is unaware of all
13 such prescriptions that a patient is receiving, includ-
14 ing abuse, improper use, and illegal distribution.

15 (4) Such misuse imposes substantial and detri-
16 mental effects on the health and welfare of the
17 American people.

18 (5) Currently there is no national databank
19 that health care practitioners and pharmacists who,
20 respectively, prescribe and dispense schedule II, III,
21 and IV controlled substances can access to deter-
22 mine whether a particular prescription is medically
23 unnecessary.

24 (6) A national electronic databank, supported
25 by State databanks where they are established under

1 State law, would allow providers to access the infor-
2 mation necessary to ascertain that a particular pre-
3 scription may be unnecessary or the subject of mis-
4 use.

5 (7) A major portion of the use and misuse of
6 schedule II, III, and IV controlled substances in-
7 volves interstate and foreign commerce.

8 (8) Schedule II, III, and IV controlled sub-
9 stances dispensed intrastate cannot be differentiated
10 from schedule II, III, and IV controlled substances
11 that are dispensed interstate, and have significant
12 interstate effects.

13 **SEC. 3. ELECTRONIC MONITORING SYSTEM FOR DIS-**
14 **PENSING CONTROLLED SUBSTANCES.**

15 Part P of title III of the Public Health Service Act
16 (42 U.S.C. 280g et seq.) is amended by adding after sec-
17 tion 399N the following:

18 **“SEC. 399O. ELECTRONIC MONITORING SYSTEM FOR DIS-**
19 **PENSING CONTROLLED SUBSTANCES.**

20 “(a) ESTABLISHMENT.—The Secretary shall estab-
21 lish an electronic system for practitioner monitoring of the
22 dispensing of any schedule II, III, or IV controlled sub-
23 stance involving patients under their care.

1 “(b) NO FEE OR TAX.—A practitioner shall not be
2 required to pay a fee or tax in connection with the system
3 established under subsection (a).

4 “(c) REPORTING REQUIREMENT.—Every dispenser
5 shall report to the Secretary the information required by
6 this section in a timely manner as prescribed by the Sec-
7 retary, except that reporting shall not be required for—

8 “(1) a drug administered directly to a patient;
9 or

10 “(2) a drug dispensed in a quantity limited to
11 an amount adequate to treat the patient for 48
12 hours or less.

13 “(d) INFORMATION TO BE REPORTED.—The Sec-
14 retary shall determine by regulation the information to be
15 reported under subsection (a) for each schedule II, III,
16 or IV controlled substance. Such information shall include
17 the following:

18 “(1) Patient identifier.

19 “(2) Drug dispensed.

20 “(3) Date of dispensing.

21 “(4) Quantity dispensed.

22 “(5) Number of refills ordered.

23 “(6) Practitioner who signed the prescription.

24 “(7) Dispenser.

1 “(e) ELECTRONIC FORMAT.—The Secretary shall
2 specify the electronic format for the reporting of informa-
3 tion under subsection (a), and may waive the requirement
4 of such format with respect to an individual dispenser.

5 “(f) PROVISION OF INFORMATION.—The Secretary
6 may provide information from the system established
7 under subsection (a) and, in the case of a request under
8 paragraph (2), compilations of such information, in re-
9 sponse to a request by—

10 “(1) a practitioner who certifies that the re-
11 quested information is for the purpose of providing
12 medical or pharmaceutical treatment or evaluating
13 the need for such treatment to a bona fide current
14 patient; or

15 “(2) any local, State, or Federal law enforce-
16 ment, narcotics control, licensure, disciplinary, or
17 program authority, who certifies that—

18 “(A) the requested information is related
19 to an investigation or proceeding involving the
20 unlawful diversion or misuse of a schedule II,
21 III, or IV substance, and the authority has rea-
22 sonable cause to conclude that such information
23 will further the purpose of the investigation or
24 assist in the proceeding; or

1 “(B) the requested information is nec-
2 essary for research purposes, but only in the
3 case of research to be conducted by the Depart-
4 ment of Health and Human Services, a State
5 medicaid program, or the Drug Enforcement
6 Administration, and the intended purpose of the
7 research is related to a function committed to
8 such agency by law that is not investigative in
9 nature.

10 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to restrict the ability of any author-
12 ity, including any local, State, or Federal law enforcement,
13 narcotics control, licensure, disciplinary, or program au-
14 thority, to secure information as otherwise authorized by
15 law.

16 “(h) LIMITATION.—The Secretary shall make reason-
17 able efforts to limit the information provided pursuant to
18 a valid request under subsection (f) to the minimum nec-
19 essary to accomplish the intended purpose of the request.
20 The Secretary shall also make reasonable efforts to imple-
21 ment a real-time electronic system, as consistent with any
22 available appropriated funds. Reports or communications
23 made under subsections (c), (f)(1), or (f)(2)(A) shall not,
24 in any event, be made to or by the Secretary more than
25 1 week after the antecedent or triggering request or event.

1 “(i) SUBSEQUENT TRANSFER OF INFORMATION.—A
2 person who, pursuant to subsection (f), receives data or
3 any report of the system from the Secretary shall not pro-
4 vide the information to any other person or entity except
5 by order of a court of competent jurisdiction or other legal
6 authority, by written patient authorization as authorized
7 under section 164.508(b) of title 45, Code of Federal Reg-
8 ulations, or any successor regulations, or as otherwise au-
9 thorized or permitted by the Health Insurance Portability
10 and Accountability Act of 1996. The provisions of sub-
11 sections (f), (g), and (h) are deemed to comply with the
12 Health Insurance Portability and Accountability Act of
13 1996 and regulations promulgated thereunder. This sec-
14 tion shall not prevent the disclosure of information by a
15 local, State, or Federal law enforcement, narcotics control,
16 licensure, disciplinary, or program authority to district at-
17 torneys, attorneys general, and others, in furtherance of
18 criminal investigations or prosecutions, or licensure, dis-
19 ciplinary, or other judicial or administrative proceedings
20 within their respective jurisdictions.

21 “(j) PENALTIES.—

22 “(1) Any dispenser who knowingly fails to
23 transmit information to the Secretary as required by
24 this section shall be subject to a civil monetary pen-
25 alty of \$100 for each such failure, and a maximum

1 civil monetary penalty of \$25,000 for such failures
2 concerning any particular patient.

3 “(2) Any person who seeks or makes a knowing
4 disclosure of transmitted information by or to a per-
5 son not authorized by subsection (f) or the Health
6 Insurance Portability and Accountability Act of
7 1996, or who knowingly obtains information under
8 this section not relating to a bona fide specific cur-
9 rent patient, shall be subject to a civil monetary pen-
10 alty of not more than \$25,000 for each such viola-
11 tion.

12 “(k) STATE MONITORING SYSTEM.—A State may
13 elect to have its own prescription monitoring system, sub-
14 ject to its own rules and regulations, operating in its juris-
15 diction to the exclusion of the Federal program created
16 by this section, so long as the State system provides the
17 information required by this provision to the Federal pro-
18 gram in a fashion consistent with any requirements issued
19 by the Secretary. The Harold Rogers Prescription Moni-
20 toring Program and the funding it provides may be
21 accessed by a State electing to proceed under this provi-
22 sion. This mechanism is intended to encourage States to
23 develop systems that may operate to provide additional in-
24 formation and experience that will assist in the refinement
25 of both the Federal and State programs.

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

2 “(1) The term ‘administered directly to a pa-
3 tient’ means the direct application of a schedule II,
4 III, or IV controlled substance to the body of a pa-
5 tient by a practitioner or by the practitioner’s agent
6 in the practitioner’s presence, whether such applica-
7 tion is by injection, inhalation, ingestion, or any
8 other means.

9 “(2) The term ‘agent’ means an authorized per-
10 son who acts on behalf of or at the direction of a
11 practitioner.

12 “(3) The term ‘dispense’ means to deliver a
13 schedule II, III, or IV controlled substance to an ul-
14 timate user pursuant to the lawful order of a practi-
15 tioner.

16 “(4) The term ‘dispenser’ means a practitioner
17 who so delivers a schedule II, III, or IV controlled
18 substance to an ultimate user.

19 “(5) The term ‘local, State, or Federal law en-
20 forcement, narcotics control, licensure, disciplinary,
21 or program authority’ means—

22 “(A) any State or local officer authorized
23 under State or local law who is employed as an
24 investigative agent of a State or local narcotics
25 control agency;

1 “(B) the Drug Enforcement Administra-
2 tion;

3 “(C) the executive director or chief investi-
4 gator, as designated by each board, of the State
5 boards of podiatry, dentistry, pharmacy, med-
6 ical licensure, osteopathic examiners, veterinary
7 medical examiners, nursing, or other boards
8 representing appropriate health care-related dis-
9 ciplines, but only with respect to information
10 relevant to licensees of the respective boards;

11 “(D) the Department of Health and
12 Human Services;

13 “(E) a State medicaid program;

14 “(F) a properly convened Federal or State
15 grand jury or other judicial authority pursuant
16 to an appropriately and properly issued sub-
17 poena; or

18 “(G) any contractor selected by the Sec-
19 retary to establish or maintain the prescription
20 database if the Secretary imposes appropriate
21 restrictions on such contractor and its per-
22 sonnel.

23 “(6) The term ‘patient identifier’ means the pa-
24 tient’s—

25 “(A) full name;

1 “(B) address, including zip code;

2 “(C) date of birth; and

3 “(D) social security number or alternative
4 identification number.

5 “(7) The term ‘practitioner’ means a physician,
6 nurse practitioner, clinical nurse specialist, physician
7 assistant, dentist, veterinarian, pharmacist, hospital,
8 or other person licensed, registered, or otherwise
9 permitted under Federal or State law to distribute,
10 dispense, or administer a controlled substance in the
11 course of professional practice.

12 “(8) The term ‘schedule II, III, or IV controlled
13 substance’ means a controlled substance (as that
14 term is defined in section 102 of the Controlled Sub-
15 stances Act) included in schedule II, III, or IV of
16 section 202 of such Act.”.

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