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107TH CONGRESS
2D SESSION

H. R. 5503

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 30, 2002

Mr. WHITFIELD (for himself, Mr. PALLONE, Mr. SESSIONS, Mr. KLECZKA, Mr. FLETCHER, Mr. PASCRELL, and Mr. STUPAK) 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 establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National All Schedules Prescription Electronic Reporting Act of 2002''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The Harold Rogers Prescription Monitoring Program has supplied and will continue to supply critically important information and experience regarding effective prescription drug monitoring practices.

(2) Schedule II, III, and IV controlled substances have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(3) Schedule II, III, and IV controlled substances have a moderate to high potential for misuse when the prescribing practitioner is unaware of all such prescriptions that a patient is receiving, including abuse, improper use, and illegal distribution.

(4) Such misuse imposes substantial and detrimental effects on the health and welfare of the American people.

(5) Currently there is no national databank that health care practitioners and pharmacists who, respectively, prescribe and dispense schedule II, III, and IV controlled substances can access to determine whether a particular prescription is medically unnecessary.

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

State law, would allow providers to access the information necessary to ascertain that a particular prescription may be unnecessary or the subject of misuse.

(7) A major portion of the use and misuse of schedule II, III, and IV controlled substances involves interstate and foreign commerce.

(8) Schedule II, III, and IV controlled substances dispensed intrastate cannot be differentiated from schedule II, III, and IV controlled substances that are dispensed interstate, and have significant interstate effects.

SEC. 3. ELECTRONIC MONITORING SYSTEM FOR DISPENSING CONTROLLED SUBSTANCES.

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

"SEC. 399O. ELECTRONIC MONITORING SYSTEM FOR DISPENSING CONTROLLED SUBSTANCES.

''(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance involving patients under their care.

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

''(c) REPORTING REQUIREMENT.—Every dispenser shall report to the Secretary the information required by this section in a timely manner as prescribed by the Secretary, except that reporting shall not be required for—

''(1) a drug administered directly to a patient; or

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

''(d) INFORMATION TO BE REPORTED.—The Secretary shall determine by regulation the information to be reported under subsection (a) for each schedule II, III, or IV controlled substance. Such information shall include the following:

''(1) Patient identifier.

''(2) Drug dispensed.

''(3) Date of dispensing.

''(4) Quantity dispensed.

''(5) Number of refills ordered.

''(6) Practitioner who signed the prescription.

''(7) Dispenser.

''(e) ELECTRONIC FORMAT.—The Secretary shall specify the electronic format for the reporting of information under subsection (a), and may waive the requirement of such format with respect to an individual dispenser.

''(f) PROVISION OF INFORMATION.—The Secretary may provide information from the system established under subsection (a) and, in the case of a request under paragraph (2), compilations of such information, in response to a request by—

''(1) a practitioner who certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient; or

''(2) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies that—

''(A) the requested information is related to an investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and the authority has reasonable cause to conclude that such information will further the purpose of the investigation or assist in the proceeding; or

''(B) the requested information is necessary for research purposes, but only in the case of research to be conducted by the Department of Health and Human Services, a State medicaid program, or the Drug Enforcement Administration, and the intended purpose of the research is related to a function committed to such agency by law that is not investigative in nature.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to secure information as otherwise authorized by law.

''(h) LIMITATION.—The Secretary shall make reasonable efforts to limit the information provided pursuant to a valid request under subsection (f) to the minimum necessary to accomplish the intended purpose of the request. The Secretary shall also make reasonable efforts to implement a real-time electronic system, as consistent with any available appropriated funds. Reports or communications made under subsections (c), (f)(1), or (f)(2)(A) shall not, in any event, be made to or by the Secretary more than 1 week after the antecedent or triggering request or event.

''(i) SUBSEQUENT TRANSFER OF INFORMATION.—A person who, pursuant to subsection (f), receives data or any report of the system from the Secretary shall not provide the information to any other person or entity except by order of a court of competent jurisdiction or other legal authority, by written patient authorization as authorized under section 164.508(b) of title 45, Code of Federal Regulations, or any successor regulations, or as otherwise authorized or permitted by the Health Insurance Portability and Accountability Act of 1996. The provisions of subsections (f), (g), and (h) are deemed to comply with the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder. This section shall not prevent the disclosure of information by a local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority to district attorneys, attorneys general, and others, in furtherance of criminal investigations or prosecutions, or licensure, disciplinary, or other judicial or administrative proceedings within their respective jurisdictions.

''(j) PENALTIES.—

''(1) Any dispenser who knowingly fails to transmit information to the Secretary as required by this section shall be subject to a civil monetary penalty of $100 for each such failure, and a maximum

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

''(2) Any person who seeks or makes a knowing disclosure of transmitted information by or to a person not authorized by subsection (f) or the Health Insurance Portability and Accountability Act of 1996, or who knowingly obtains information under this section not relating to a bona fide specific current patient, shall be subject to a civil monetary penalty of not more than $25,000 for each such violation.

''(k) STATE MONITORING SYSTEM.—A State may elect to have its own prescription monitoring system, subject to its own rules and regulations, operating in its jurisdiction to the exclusion of the Federal program created by this section, so long as the State system provides the information required by this provision to the Federal program in a fashion consistent with any requirements issued by the Secretary. The Harold Rogers Prescription Monitoring Program and the funding it provides may be accessed by a State electing to proceed under this provision. This mechanism is intended to encourage States to develop systems that may operate to provide additional information and experience that will assist in the refinement of both the Federal and State programs.

''(l) DEFINITIONS.—For purposes of this section:

''(1) The term 'administered directly to a patient' means the direct application of a schedule II, III, or IV controlled substance to the body of a patient by a practitioner or by the practitioner's agent in the practitioner's's presence, whether such application is by injection, inhalation, ingestion, or any other means.

''(2) The term 'agent' means an authorized person who acts on behalf of or at the direction of a practitioner.

''(3) The term 'dispense' means to deliver a schedule II, III, or IV controlled substance to an ultimate user pursuant to the lawful order of a practitioner.

''(4) The term 'dispenser' means a practitioner who so delivers a schedule II, III, or IV controlled substance to an ultimate user.

''(5) The term ''local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority'' means—

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

''(B) the Drug Enforcement Administration;

''(C) the executive director or chief investigator, as designated by each board, of the State boards of podiatry, dentistry, pharmacy, medical licensure, osteopathic examiners, veterinary medical examiners, nursing, or other boards representing appropriate health care-related disciplines, but only with respect to information relevant to licensees of the respective boards;

''(D) the Department of Health and Human Services;

''(E) a State medicaid program;

''(F) a properly convened Federal or State grand jury or other judicial authority pursuant to an appropriately and properly issued subpoena; or

''(G) any contractor selected by the Secretary to establish or maintain the prescription database if the Secretary imposes appropriate restrictions on such contractor and its personnel.

''(6) The term 'patient identifier' means the patient's—

''(A) full name;

"(B) address, including zip code;

"(C) date of birth; and

"(D) social security number or alternative identification number.

"(7) The term 'practitioner' means a physician, nurse practitioner, clinical nurse specialist, physician assistant, dentist, veterinarian, pharmacist, hospital, or other person licensed, registered, or otherwise permitted under Federal or State law to distribute, dispense, or administer a controlled substance in the course of professional practice.

"(8) The term 'schedule II, III, or IV controlled substance' means a controlled substance (as that term is defined in section 102 of the Controlled Substances Act) included in schedule II, III, or IV of section 202 of such Act.".

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