II

108TH CONGRESS
2D SESSION

H. R. 3015

IN THE SENATE OF THE UNITED STATES

OCTOBER 6, 2004
Received

AN ACT

To provide for the establishment of a controlled substance monitoring program in each State.

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 2004''.

SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.

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. CONTROLLED SUBSTANCE MONITORING PROGRAM.

''(a) FORMULA GRANTS.—

''(1) IN GENERAL.—Each fiscal year, the Secretary shall make a payment to each State with an application approved under this section for the purpose of establishing and implementing a controlled substance monitoring program under this section.

''(2) DETERMINATION OF AMOUNT.—In making payments under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this paragraph

after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

''(b) APPLICATION APPROVAL PROCESS.—

''(1) IN GENERAL.—To seek a grant under this section, a State shall submit an application at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

''(A) a budget cost estimate for the State's controlled substance monitoring program;

''(B) proposed standards for security for information handling and for the database maintained by the State under subsection (d) generally including efforts to use appropriate encryption technology or other such technology;

''(C) proposed standards for meeting the uniform electronic format requirement of subsection (g);

''(D) proposed standards for availability of information and limitation on access to program personnel;

''(E) proposed standards for access to the database, and procedures to ensure database accuracy;

''(F) proposed standards for redisclosure of information;

''(G) proposed penalties for illegal redisclosure of information; and

''(H) assurances of compliance with all other requirements of this section.

''(2) APPROVAL OR DISAPPROVAL.—Not later than 90 days after the submission by a State of an application under paragraph (1), the Secretary shall approve or disapprove the application. The Secretary shall approve the application if the State demonstrates to the Secretary that the State will establish and implement or operate a controlled substance monitoring program in accordance with this section.

''(3) WITHDRAWAL OF AUTHORIZATION.—If a State fails to implement a controlled substance monitoring program in accordance with this section—

''(A) the Secretary shall give notice of the failure to the State; and

''(B) if the State fails to take corrective action within a reasonable period of time, the Secretary shall withdraw any approval of the State's application under this section.

''(4) VOLUNTARY DISCONTINUANCE.—A funding agreement for the receipt of a payment under

this section is that the State involved will give a reasonable period of notice to the Secretary before ceasing to implement or operate a controlled substance monitoring program under this section. The Secretary shall determine the period of notice that is reasonable for purposes of this paragraph.

''(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement a controlled substance monitoring program under this section, a funding agreement for the receipt of a payment under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall payment as the remaining time period for expending the payment bears to the overall time period for expending the payment (as specified by the Secretary at the time of the payment).

''(c) REPORTING REQUIREMENTS.—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:

''(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user or re-

search subject not later than 1 week after the date of such dispensing.

''(2) The State may exclude from the reporting requirement of this subsection—

''(A) the direct administration of a controlled substance to the body of an ultimate user or research subject;

''(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user or research subject involved for 48 hours or less; or

''(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

''(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

''(A) Drug Enforcement Administration Registration Number of the dispenser.

''(B) Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug.

''(C) Name, address, and telephone number of the ultimate user or research subject.

"(D) Identification of the drug by a national drug code number.

"(E) Quantity dispensed.

"(F) Estimated number of days for which such quantity should last.

"(G) Number of refills ordered.

"(H) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

"(I) Date of the dispensing.

"(J) Date of origin of the prescription.

"(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (g), except that the State may waive the requirement of such format with respect to an individual dispenser.

"(5) The State shall automatically share information reported under this subsection with another State with an application approved under this section if the information concerns—

"(A) the dispensing of a controlled substance to an ultimate user or research subject who resides in such other State; or

''(B) the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

''(6) The State may notify the appropriate authorities responsible for drug diversion investigation if information in the database maintained by the State under subsection (d) indicates an unlawful diversion or misuse of a controlled substance.

''(d) DATABASE.—In implementing a controlled substance monitoring program under this section, a State shall comply with the following:

''(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (c).

''(2) The database must be searchable by any field or combination of fields.

''(3) The State shall include reported information in the database at such time and in such manner as the Secretary determines appropriate, with appropriate safeguards for ensuring the accuracy and completeness of the database.

''(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

''(e) PROVISION OF INFORMATION.—Subject to subsection (f), in implementing a controlled substance monitoring program under this section, a State may provide information from the database established under subsection (d) and, in the case of a request under paragraph (3), summary statistics of such information, in response to a request by—

''(1) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, 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;

''(2) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

''(3) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement

Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

''(4) any agent of another State, who certifies that the State has an application approved under this section and the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

''(f) LIMITATIONS.—In implementing a controlled substance monitoring program under this section, a State—

''(1) shall make reasonable efforts to limit the information provided pursuant to a valid request under subsection (e) to the minimum necessary to accomplish the intended purpose of the request; and

''(2) shall not provide any individually identifiable information in response to a request under subsection (e)(3).

''(g) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and provision of information under this section.

''(h) RULES OF CONSTRUCTION.—

''(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—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 perform functions otherwise authorized by law.

''(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

''(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

''(4) CERTAIN CONFIDENTIALITY REQUIREMENTS.—Nothing in this section shall be construed as superceding the confidentiality requirements of programs defined by and subject to part 2 of title 42, Code of Federal Regulations.

''(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

''(i) RELATION TO HIPAA.—Except to the extent inconsistent with this section, the provision of information

pursuant to subsection (c)(5), (c)(6), or (e) and the subsequent transfer of such information are subject to any requirement that would otherwise apply under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(j) PREFERENCE.—Beginning January 1, 2007, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) to a State, shall give preference to any State with an application approved under this section.

''(k) STUDY.—Not later than 2 years after the date of the enactment of this section, the Secretary shall—

''(1) complete a study that—

''(A) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

''(B) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program; and

''(C) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring

program in each State receiving a grant for the establishment or operation of such program, and a comparison to the privacy requirements that apply to covered entities under regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, along with any recommendations for additional requirements for protection of this information; and

''(2) submit a report to the Congress on the results of the study.

''(l) ADVISORY COUNCIL.—

''(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment and implementation of a controlled substance monitoring program under this section.

''(2) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

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

''(1) The term 'bona fide patient' means an individual who is a patient of the dispenser or practitioner involved.

''(2) The term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

''(3) The term 'dispense' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

''(4) The term 'dispenser' means a physician, pharmacist, or other individual who dispenses a controlled substance to an ultimate user or research subject.

''(5) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

''(6) The term 'State' means each of the 50 States and the District of Columbia.

''(7) The term 'ultimate user' means a person who has lawfully obtained, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

''(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

''(1) $25,000,000 for each of fiscal years 2006 and 2007; and

''(2) $15,000,000 for each of fiscal years 2008, 2009, and 2010.''.

Passed the House of Representatives October 5, 2004.

Attest: JEFF TRANDAHL,

Clerk.