II

108TH CONGRESS
2D SESSION

S. 3013

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 19, 2004

Mr. SESSIONS (for himself, Mr. DURBIN, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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) GRANTS.—

"(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

"(A) to establish and implement a State controlled substance monitoring program; or

"(B) to make improvements to an existing State controlled substance monitoring program.

"(2) DETERMINATION OF AMOUNT.—

"(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 0.5 percent of the amount appropriated to carry out this section for that fiscal year.

"(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and

remaining after amounts are made available under paragraph (1) 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 subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

''(3) TERM OF CERTAIN GRANTS.—Grants awarded under this section shall be for a term of 1 year.

''(b) DEVELOPMENT OF MINIMUM STANDARDS AND RECOMMENDATIONS.—

''(1) IN GENERAL.—Not later than 30 days after the date of enactment of this section, the Secretary shall—

''(A) develop minimum standards for use by States in submitting their proposed standards under clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A); and

''(B) develop recommendations with respect to appropriate penalties for the provision

or use of information in violation of applicable Federal, State, or local law or regulation.

''(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall report to Congress on the recommendations developed under paragraph (1)(B).

''(c) APPLICATION APPROVAL PROCESS.—

''(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit, and have approved in accordance with paragraph (2), an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

''(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

''(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

''(ii) proposed standards for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or

other appropriate technology to protect the security of such information;

''(iii) an agreement to adopt, to the extent practicable, applicable health information technology standards, as determined by the Secretary;

''(iv) proposed standards for meeting the uniform electronic format requirement of subsection (h);

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

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

''(vii) proposed standards for the provision of information, including a description of the certification process to be applied to requests for information under subsection (f);

''(viii) proposed penalties for the provision or use of information in violation of applicable Federal, State, or local law or regulation; and

''(ix) assurances of compliance with all other requirements of this section; or

''(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

''(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

''(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the standards and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

''(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program, including—

''(I) the technical achievement of information sharing between the two programs;

''(II) measures to ensure that interoperability activities carried out under this subsection are in compli-

ance with the requirements of subparagraph (A);

''(III) measures to ensure that proposed standards for information access will be enforced for shared information; and

''(IV) the completion of interstate legal compacts necessary for such information sharing; and

''(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

''(2) APPROVAL OR DISAPPROVAL.—

''(A) IN GENERAL.—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, or request additional information as provided under subparagraph (C). The Secretary may disapprove an application that contains a statement described in paragraph (1)(B)(iv), or request additional information with respect to such a statement, if the Secretary determines

that the approval of such application would result in the implementation of a State program that substantially fails to meet the goals and objectives of this section.

''(B) APPROVAL.—The Secretary shall approve an application submitted under paragraph (1) only if—

''(i) the plans contained in the application meet the standards developed by the Secretary under subsection (b); and

''(ii) the State demonstrates to the Secretary that the State will establish and implement or improve a controlled substance monitoring program in accordance with this section.

''(C) ADDITIONAL INFORMATION.—With respect to an application submitted by a State under paragraph (1), the Secretary may, during the 90-day period referred to in subparagraph (A), request that the State provide additional information with respect to the State program. If such a request is made after the expiration of the 60-day period beginning on the date on which the application is submitted, the period under subparagraph (A) for approval or dis-

approval by the Secretary shall be extended for an additional 30 days.

''(3) WITHDRAWAL OF AUTHORIZATION.—Except to the extent that a State is excused from compliance with a requirement or standard as a result of the approval by the Secretary of a statement under paragraph (1)(B)(iv) or under subsection (d), if a State fails to implement or improve a controlled substance monitoring program in accordance with this section or fails to comply with the standards developed under this subsection—

''(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 grant 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 or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

''(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, 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 research 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 or such contact information of the ultimate user or

research subject as the Secretary determines appropriate.

''(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 (h), except that the State may waive the requirement of such format with respect to an individual dispenser.

''(e) DATABASE.—In implementing or improving 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 (d).

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

''(3) The State shall include reported information in the database in a manner consistent with standards established by the Secretary, 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.

''(f) PROVISION OF INFORMATION.—

''(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may provide information from the database established under subsection (e) and, in the case of a request under paragraph (3), summary statistics of such information, in response to a request by—

''(A) 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;

''(B) 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;

''(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

''(D) 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

''(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

''(i) the State has an application approved under this section; and

''(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

''(2) DRUG DIVERSION.—A State that elects to exercise its authority to notify the appropriate authorities responsible for drug diversion investigations if information in the database maintained by the State under subsection (e) is suggestive of an unlawful diversion or misuse of a controlled substance, is encouraged to develop any such notification program in consultation with representatives of the medical community, including physicians and pharmacists or other interested stakeholders.

''(g) LIMITATIONS.—In implementing or improving 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 (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

''(2) shall limit information provided in response to a request under subsection (f)(1)(D) to information provided in a form and manner that prevents the identification of a provider or patient.

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

''(i) 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 pre-

empting any State from imposing any additional privacy protections.

''(4) CERTAIN CONFIDENTIALITY REQUIREMENTS.—Nothing in this section shall be construed as superseding 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.

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

''(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 progress of States in achieving interoperability between controlled

substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

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

''(D) 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

''(E) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance

monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; 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, implementation, or improvement 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 'interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user or research subject who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

''(6) The term 'nonidentifiable information' means information that is provided in a form and manner that prevents the identification of a provider or patient.

''(7) 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.

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

''(9) 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.''.

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