

Calendar No. 187

109TH CONGRESS
1ST SESSION**S. 518****[Report No. 109–117]**

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

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2005

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

JULY 29, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]**A BILL**

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

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 2005~~”.

1 **SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

2 Part P of title III of the Public Health Service Act
3 (42 U.S.C. 280g et seq.) is amended by adding after sec-
4 tion 399N the following:

5 **“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-**
6 **GRAM.**

7 **“(a) GRANTS.—**

8 **“(1) IN GENERAL.—**Each fiscal year, the Sec-
9 retary shall award a grant to each State with an ap-
10 plication approved under this section to enable the
11 State—

12 **“(A)** to establish and implement a State
13 controlled substance monitoring program; or

14 **“(B)** to make improvements to an existing
15 State controlled substance monitoring program.

16 **“(2) DETERMINATION OF AMOUNT.—**

17 **“(A) MINIMUM AMOUNT.—**In making pay-
18 ments under a grant under paragraph (1) for
19 a fiscal year, the Secretary shall allocate to
20 each State with an application approved under
21 this section an amount that equals 0.5 percent
22 of the amount appropriated to carry out this
23 section for that fiscal year.

24 **“(B) ADDITIONAL AMOUNTS.—**In making
25 payments under a grant under paragraph (1)
26 for a fiscal year, the Secretary shall allocate to

1 each State with an application approved under
 2 this section an additional amount which bears
 3 the same ratio to the amount appropriated to
 4 carry out this section for that fiscal year and
 5 remaining after amounts are made available
 6 under paragraph (1) as the number of phar-
 7 macies of the State bears to the number of
 8 pharmacies of all States with applications ap-
 9 proved under this section (as determined by the
 10 Secretary); except that the Secretary may ad-
 11 just the amount allocated to a State under this
 12 subparagraph after taking into consideration
 13 the budget cost estimate for the State's con-
 14 trolled substance monitoring program.

15 ~~“(3) TERM OF CERTAIN GRANTS.—~~Grants
 16 awarded under this section shall be for a term of 18
 17 months.

18 ~~“(b) DEVELOPMENT OF MINIMUM STANDARDS AND~~
 19 RECOMMENDATIONS.—

20 ~~“(1) IN GENERAL.—~~Not later than 30 days
 21 after the date of enactment of this section, the Sec-
 22 retary shall—

23 ~~“(A) develop minimum standards for use~~
 24 by States in submitting their proposed stand-

ards under clauses (ii), (v), (vi), and (vii) of
subsection (e)(1)(A); and

“(B) develop recommendations with re-
spect 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 devel-
oped under paragraph (1)(B) and the extent to
which existing penalties meet, exceed, or fall short of
such recommendations.

“(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 infor-
mation 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)—

1 “(i) a budget cost estimate for the
2 controlled substance monitoring program
3 to be implemented under the grant;

4 “(ii) proposed standards for security
5 for information handling and for the data-
6 base maintained by the State under sub-
7 section (c) generally including efforts to
8 use appropriate encryption technology or
9 other appropriate technology to protect the
10 security of such information;

11 “(iii) an agreement to adopt, to the
12 extent practicable, applicable health infor-
13 mation technology standards, as deter-
14 mined by the Secretary;

15 “(iv) proposed standards for meeting
16 the uniform electronic format requirement
17 of subsection (h);

18 “(v) proposed standards for avail-
19 ability of information and limitation on ac-
20 cess to program personnel;

21 “(vi) proposed standards for access to
22 the database, and procedures to ensure
23 database accuracy;

24 “(vii) proposed standards for the pro-
25 vision of information, including a descrip-

tion 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 compliance 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 ap-

plication 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 disapproval 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.

1 “(4) VOLUNTARY DISCONTINUANCE.—A fund-
 2 ing agreement for the receipt of a grant under this
 3 section is that the State involved will give a reason-
 4 able period of notice to the Secretary before ceasing
 5 to implement or operate a controlled substance mon-
 6 itoring program under this section. The Secretary
 7 shall determine the period of notice that is reason-
 8 able for purposes of this paragraph.

9 “(5) RETURN OF FUNDS.—If the Secretary
 10 withdraws approval of a State’s application under
 11 this section, or the State chooses to cease to imple-
 12 ment or improve a controlled substance monitoring
 13 program under this section, a funding agreement for
 14 the receipt of a grant under this section is that the
 15 State will return to the Secretary an amount which
 16 bears the same ratio to the overall grant as the re-
 17 maining time period for expending the grant funds
 18 bears to the overall time period for expending the
 19 grant (as specified by the Secretary at the time of
 20 the grant).

21 “(d) REPORTING REQUIREMENTS.—In implementing
 22 or improving a controlled substance monitoring program
 23 under this section, a State shall comply, or with respect
 24 to a State that applies for a grant under subsection
 25 (a)(1)(B) submit to the Secretary for approval a state-

1 ment of why such compliance is not feasible or is contrary
2 to the best interests of public health in such State, with
3 the following:

4 “(1) The State shall require dispensers to re-
5 port to such State each dispensing in the State of
6 a controlled substance to an ultimate user not later
7 than 1 week after the date of such dispensing.

8 “(2) The State may exclude from the reporting
9 requirement of this subsection—

10 “(A) the direct administration of a con-
11 trolled substance to the body of an ultimate
12 user;

13 “(B) the dispensing of a controlled sub-
14 stance in a quantity limited to an amount ade-
15 quate to treat the ultimate user involved for 48
16 hours or less; or

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

21 “(3) The information to be reported under this
22 subsection with respect to the dispensing of a con-
23 trolled substance shall include the following:

24 “(A) Drug Enforcement Administration
25 Registration Number of the dispenser.

1 “(B) Drug Enforcement Administration
2 Registration Number and name of the practi-
3 tioner who prescribed the drug.

4 “(C) Name, address, and telephone num-
5 ber of the ultimate user or such contact infor-
6 mation of the ultimate user as the Secretary de-
7 termines appropriate.

8 “(D) Identification of the drug by a na-
9 tional drug code number.

10 “(E) Quantity dispensed.

11 “(F) Estimated number of days for which
12 such quantity should last.

13 “(G) Number of refills ordered.

14 “(H) Whether the drug was dispensed as
15 a refill of a prescription or as a first-time re-
16 quest.

17 “(I) Date of the dispensing.

18 “(J) Date of origin of the prescription.

19 “(4) The State shall require dispensers to re-
20 port information under this section in accordance
21 with the electronic format specified by the Secretary
22 under subsection (h), except that the State may
23 waive the requirement of such format with respect to
24 an individual dispenser.

1 “(e) DATABASE.—In implementing or improving a
2 controlled substance monitoring program under this sec-
3 tion, a State shall comply with the following:

4 “(1) The State shall establish and maintain an
5 electronic database containing the information re-
6 ported to the State under subsection (d).

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

9 “(3) The State shall include reported informa-
10 tion in the database in a manner consistent with
11 standards established by the Secretary, with appro-
12 priate safeguards for ensuring the accuracy and
13 completeness of the database.

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

17 “(f) PROVISION OF INFORMATION.—

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

1 “(A) a practitioner (or the agent thereof)
2 who certifies, under the procedures determined
3 by the State, that the requested information is
4 for the purpose of providing medical or pharma-
5 ceutical treatment or evaluating the need for
6 such treatment to a bona fide current patient;

7 “(B) any local, State, or Federal law en-
8 forcement, narcotics control, licensure, discipli-
9 nary, or program authority, who certifies, under
10 the procedures determined by the State, that
11 the requested information is related to an indi-
12 vidual investigation or proceeding involving the
13 unlawful diversion or misuse of a schedule II,
14 III, or IV substance, and such information will
15 further the purpose of the investigation or as-
16 sist in the proceeding;

17 “(C) the controlled substance monitoring
18 program of another State or group of States
19 with whom the State has established an inter-
20 operability agreement;

21 “(D) any agent of the Department of
22 Health and Human Services, a State medicaid
23 program, a State health department, or the
24 Drug Enforcement Administration who certifies
25 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 enti-
 ty 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 ap-
 proved 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 au-
 thorities responsible for drug diversion investigations
 if information in the database maintained by the
 State under subsection (c) is suggestive of an unlaw-
 ful diversion or misuse of a controlled substance, is
 encouraged to develop any such notification program
 in consultation with representatives of the medical

1 community, including physicians and pharmacists or
 2 other interested stakeholders.

3 ~~“(g) LIMITATIONS.—In implementing or improving a~~
 4 ~~controlled substance monitoring program under this sec-~~
 5 ~~tion, a State—~~

6 ~~“(1) shall make reasonable efforts to limit the~~
 7 ~~information provided pursuant to a valid request~~
 8 ~~under subsection (f)(1) to the minimum necessary to~~
 9 ~~accomplish the intended purpose of the request; and~~

10 ~~“(2) shall limit information provided in re-~~
 11 ~~sponse to a request under subsection (f)(1)(D) to in-~~
 12 ~~formation provided in a form and manner that pre-~~
 13 ~~vents the identification of a provider or patient.~~

14 ~~“(h) ELECTRONIC FORMAT.—The Secretary shall~~
 15 ~~specify a uniform electronic format for the reporting, shar-~~
 16 ~~ing, and provision of information under this section.~~

17 ~~“(i) RULES OF CONSTRUCTION.—~~

18 ~~“(1) FUNCTIONS OTHERWISE AUTHORIZED BY~~
 19 ~~LAW.—Nothing in this section shall be construed to~~
 20 ~~restrict the ability of any authority, including any~~
 21 ~~local, State, or Federal law enforcement, narcotics~~
 22 ~~control, licensure, disciplinary, or program authority,~~
 23 ~~to perform functions otherwise authorized by law.~~

24 ~~“(2) NO PREEMPTION.—Nothing in this section~~
 25 ~~shall be construed as preempting any State law, ex-~~

1 cept that no such law may relieve any person of a
2 requirement otherwise applicable under this Act.

3 ~~“(3) ADDITIONAL PRIVACY PROTECTIONS.—~~

4 Nothing in this section shall be construed as pre-
5 empting any State from imposing any additional pri-
6 vaey protections.

7 ~~“(4) CERTAIN CONFIDENTIALITY REQUIRE-~~

8 MENTS.—Nothing in this section shall be construed
9 as superseding the confidentiality requirements of
10 programs defined by and subject to part 2 of title
11 42, Code of Federal Regulations.

12 ~~“(5) NO FEDERAL PRIVATE CAUSE OF AC-~~

13 TION.—Nothing in this section shall be construed to
14 create a Federal private cause of action.

15 ~~“(j) RELATION TO HIPAA.—Except to the extent in-~~

16 consistent with this section, the provision of information
17 pursuant to subsection (f) and the subsequent transfer of
18 such information are subject to any requirement that
19 would otherwise apply under the regulations promulgated
20 pursuant to section 264(e) of the Health Insurance Port-
21 ability and Accountability Act of 1996.

22 ~~“(k) STUDY.—Not later than 2 years after the date~~

23 of the enactment of this section, the Secretary shall—

24 ~~“(1) complete a study that—~~

1 “(A) determines the progress of States in
2 establishing and implementing controlled sub-
3 stance monitoring programs under this section;

4 “(B) determines the progress of States in
5 achieving interoperability between controlled
6 substance monitoring programs, including an
7 assessment of technical and legal barriers to
8 such activities and recommendations for ad-
9 dressing these barriers;

10 “(C) determines the feasibility of imple-
11 menting a real-time electronic controlled sub-
12 stance monitoring program, including the costs
13 associated with establishing such a program;
14 and

15 “(D) provides an analysis of the privacy
16 protections in place for the information re-
17 ported to the controlled substance monitoring
18 program in each State receiving a grant for the
19 establishment or operation of such program;
20 and a comparison to the privacy requirements
21 that apply to covered entities under regulations
22 promulgated pursuant to section 264(c) of the
23 Health Insurance Portability and Accountability
24 Act of 1996, along with any recommendations

1 for additional requirements for protection of
2 this information; and

3 “(E) determines the feasibility of imple-
4 menting technological alternatives to centralized
5 data storage, such as peer-to-peer file sharing
6 or data pointer systems, in controlled substance
7 monitoring programs and the potential for such
8 alternatives to enhance the privacy and security
9 of individually identifiable data; and

10 “(2) submit a report to the Congress on the re-
11 sults of the study.

12 “(1) ADVISORY COUNCIL.—

13 “(1) ESTABLISHMENT.—A State may establish
14 an advisory council to assist in the establishment,
15 implementation, or improvement of a controlled sub-
16 stance monitoring program under this section.

17 “(2) SENSE OF CONGRESS.—It is the sense of
18 the Congress that, in establishing an advisory coun-
19 cil under this subsection, a State should consult with
20 appropriate professional boards and other interested
21 parties.

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

23 “(1) The term ‘bona fide patient’ means an in-
24 dividual who is a patient of the dispenser or practi-
25 tioner involved.

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

4 “(3) The term ‘dispense’ means to deliver a
5 controlled substance to an ultimate user by, or pur-
6 suant to the lawful order of, a practitioner, irrespec-
7 tive of whether the dispenser uses the Internet or
8 other means to effect such delivery.

9 “(4) The term ‘dispenser’ means a physician,
10 pharmacist, or other individual who dispenses a con-
11 trolled substance to an ultimate user.

12 “(5) The term ‘interoperability’ with respect to
13 a State controlled substance monitoring program
14 means the ability of the program to electronically
15 share reported information, including each of the re-
16 quired report components described in subsection
17 (d), with another State if the information concerns
18 either the dispensing of a controlled substance to an
19 ultimate user who resides in such other State, or the
20 dispensing of a controlled substance prescribed by a
21 practitioner whose principal place of business is lo-
22 cated in such other State.

23 “(6) The term ‘nonidentifiable information’
24 means information that is provided in a form and

1 manner that prevents the identification of a provider
 2 or patient.

3 “(7) The term ‘practitioner’ means a physician,
 4 dentist, veterinarian, scientific investigator, phar-
 5 macy, hospital, or other person licensed, registered,
 6 or otherwise permitted, by the United States or the
 7 jurisdiction in which he or she practices or does re-
 8 search, to distribute, dispense, conduct research with
 9 respect to, administer, or use in teaching or chemical
 10 analysis, a controlled substance in the course of pro-
 11 fessional practice or research.

12 “(8) The term ‘State’ means each of the 50
 13 States and the District of Columbia.

14 “(9) The term ‘ultimate user’ means a person
 15 who has lawfully obtained, and who possesses, a con-
 16 trolled substance for his or her own use, for the use
 17 of a member of his or her household, or for the use
 18 of an animal owned by him or her or by a member
 19 of his or her household.

20 “(n) AUTHORIZATION OF APPROPRIATIONS.—To
 21 carry out this section, there are authorized to be appro-
 22 priated—

23 “(1) \$25,000,000 for each of fiscal years 2006
 24 and 2007; and

1 ~~“(2) \$15,000,000 for each of fiscal years 2008,~~
 2 ~~2009, and 2010.”.~~

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “National All Schedules*
 5 *Prescription Electronic Reporting Act of 2005”.*

6 **SEC. 2. PURPOSE.**

7 *It is the purpose of this Act to—*

8 *(1) foster the establishment of State-administered*
 9 *prescription drug monitoring systems in order to en-*
 10 *sure that health care providers have access to the ac-*
 11 *curate, timely prescription history information that*
 12 *they may use as a tool for the early identification of*
 13 *patients at risk for addiction in order to initiate ap-*
 14 *propriate medical interventions and avert the tragic*
 15 *personal, family, and community consequences of un-*
 16 *treated addiction; and*

17 *(2) establish, based on the experiences of existing*
 18 *State control substance monitoring programs, a set of*
 19 *best practices to guide the establishment of new State*
 20 *programs and the improvement of existing programs.*

21 **SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

22 *Part P of title III of the Public Health Service Act*
 23 *(42 U.S.C. 280g et seq.) is amended by adding after section*
 24 *399N the following:*

1 **“SEC. 3990. CONTROLLED SUBSTANCE MONITORING PRO-**
 2 **GRAM.**

3 “(a) *GRANTS.*—

4 “(1) *IN GENERAL.*—*Each fiscal year, the Sec-*
 5 *retary shall award a grant to each State with an ap-*
 6 *plication approved under this section to enable the*
 7 *State—*

8 “(A) *to establish and implement a State*
 9 *controlled substance monitoring program; or*

10 “(B) *to make improvements to an existing*
 11 *State controlled substance monitoring program.*

12 “(2) *DETERMINATION OF AMOUNT.*—

13 “(A) *MINIMUM AMOUNT.*—*In making pay-*
 14 *ments under a grant under paragraph (1) for a*
 15 *fiscal year, the Secretary shall allocate to each*
 16 *State with an application approved under this*
 17 *section an amount that equals 1.0 percent of the*
 18 *amount appropriated to carry out this section*
 19 *for that fiscal year.*

20 “(B) *ADDITIONAL AMOUNTS.*—*In making*
 21 *payments under a grant under paragraph (1)*
 22 *for a fiscal year, the Secretary shall allocate to*
 23 *each State with an application approved under*
 24 *this section an additional amount which bears*
 25 *the same ratio to the amount appropriated to*
 26 *carry out this section for that fiscal year and re-*

1 *maintaining after amounts are made available under*
 2 *paragraph (1) as the number of pharmacies of*
 3 *the State bears to the number of pharmacies of*
 4 *all States with applications approved under this*
 5 *section (as determined by the Secretary), except*
 6 *that the Secretary may adjust the amount allo-*
 7 *cated to a State under this subparagraph after*
 8 *taking into consideration the budget cost esti-*
 9 *mate for the State's controlled substance moni-*
 10 *toring program.*

11 “(3) *TERM OF CERTAIN GRANTS.*—*Grants*
 12 *awarded under this section shall be obligated in the*
 13 *year in which funds are allotted.*

14 “(b) *DEVELOPMENT OF MINIMUM REQUIREMENTS.*—
 15 *Prior to awarding a grant under this section, but not later*
 16 *than 6 months after the date on which funds are first appro-*
 17 *priated under this section, the Secretary shall identify min-*
 18 *imum requirements for use by States in submitting their*
 19 *proposed criteria under clauses (ii), (v), (vi), and (vii) of*
 20 *subsection (c)(1)(A).*

21 “(c) *APPLICATION APPROVAL PROCESS.*—

22 “(1) *IN GENERAL.*—*To be eligible to receive a*
 23 *grant under this section, a State shall submit an ap-*
 24 *plication to the Secretary at such time, in such man-*
 25 *ner, and containing such assurances and information*

1 *as the Secretary may reasonably require. Each such*
2 *application shall include—*

3 “(A) *with respect to a State that intends to*
4 *use funds under the grant as provided for in sub-*
5 *section (a)(1)(A)—*

6 “(i) *a budget cost estimate for the con-*
7 *trolled substance monitoring program to be*
8 *implemented under the grant;*

9 “(ii) *criteria for security for informa-*
10 *tion handling and for the database main-*
11 *tained by the State under subsection (e)*
12 *generally including efforts to use appro-*
13 *propriate encryption technology or other ap-*
14 *propriate technology to protect the security*
15 *of such information;*

16 “(iii) *an agreement to adopt health in-*
17 *formation interoperability standards, in-*
18 *cluding health vocabulary and messaging*
19 *standards, that are consistent with any such*
20 *standards generated or identified by the*
21 *Secretary or his or her designee;*

22 “(iv) *criteria for meeting the uniform*
23 *electronic format requirement of subsection*
24 *(h);*

1 “(v) criteria for availability of infor-
 2 mation and limitation on access to program
 3 personnel;

4 “(vi) criteria for access to the database,
 5 and procedures to ensure database accuracy;

6 “(vii) criteria for the use and disclo-
 7 sure of information, including a description
 8 of the certification process to be applied to
 9 requests for information under subsection
 10 (f);

11 “(viii) penalties for the unauthorized
 12 use and disclosure of information in viola-
 13 tion of applicable State law or regulation;
 14 and

15 “(ix) assurances of compliance with all
 16 other requirements of this section; or

17 “(B) with respect to a State that intends to
 18 use funds under the grant as provided for in sub-
 19 section (a)(1)(B)—

20 “(i) a budget cost estimate for the con-
 21 trolled substance monitoring program to be
 22 improved under the grant;

23 “(ii) a plan for ensuring that the State
 24 controlled substance monitoring program is
 25 in compliance with the criteria and penalty

1 requirements described in clauses (ii)
2 through (viii) of subparagraph (A);

3 “(iii) a plan to enable the State con-
4 trolled substance monitoring program to
5 achieve interoperability with at least one
6 other State controlled substance monitoring
7 program; and

8 “(iv) assurances of compliance with all
9 other requirements of this section or a state-
10 ment describing why such compliance is not
11 feasible or is contrary to the best interests
12 of public health in such State.

13 “(2) *STATE LEGISLATION*.—As part of an appli-
14 cation under paragraph (1), the Secretary shall re-
15 quire the State to have enacted legislation or regula-
16 tions to permit the implementation of the State con-
17 trolled substance monitoring program and the imposi-
18 tion of appropriate penalties for the unauthorized use
19 and disclosure of information maintained in such
20 program.

21 “(3) *INTEROPERABILITY*.—If a State that sub-
22 mits an application under this subsection geographi-
23 cally borders another State that is operating a con-
24 trolled substances monitoring program under sub-
25 section (a)(1) on the date of such application, and

1 *such applicant State has not achieved interoperability*
 2 *for purposes of information sharing between its moni-*
 3 *toring program and the monitoring program of such*
 4 *border State, such applicant State shall, as part of*
 5 *the plan under paragraph (1)(B)(iii), describe the*
 6 *manner in which the applicant State will achieve*
 7 *interoperability between the monitoring programs of*
 8 *such States.*

9 *“(4) RETURN OF FUNDS.—If the Secretary with-*
 10 *draws approval of a State’s application under this*
 11 *section, or the State chooses to cease to implement or*
 12 *improve a controlled substance monitoring program*
 13 *under this section, a funding agreement for the re-*
 14 *ceipt of a grant under this section is that the State*
 15 *will return to the Secretary an amount which bears*
 16 *the same ratio to the overall grant as the remaining*
 17 *time period for expending the grant funds bears to the*
 18 *overall time period for expending the grant (as speci-*
 19 *fied by the Secretary at the time of the grant).*

20 *“(d) REPORTING REQUIREMENTS.—In implementing*
 21 *or improving a controlled substance monitoring program*
 22 *under this section, a State shall comply, or with respect*
 23 *to a State that applies for a grant under subsection*
 24 *(a)(1)(B) submit to the Secretary for approval a statement*
 25 *of why such compliance is not feasible or is contrary to*

1 *the best interests of public health in such State, with the*
 2 *following:*

3 “(1) *The State shall require dispensers to report*
 4 *to such State each dispensing in the State of a con-*
 5 *trolled substance to an ultimate user not later than*
 6 *1 week after the date of such dispensing.*

7 “(2) *The State may exclude from the reporting*
 8 *requirement of this subsection—*

9 “(A) *the direct administration of a con-*
 10 *trolled substance to the body of an ultimate user;*

11 “(B) *the dispensing of a controlled sub-*
 12 *stance in a quantity limited to an amount ade-*
 13 *quate to treat the ultimate user involved for 48*
 14 *hours or less; or*

15 “(C) *the administration or dispensing of a*
 16 *controlled substance in accordance with any*
 17 *other exclusion identified by the Secretary for*
 18 *purposes of this paragraph.*

19 “(3) *The information to be reported under this*
 20 *subsection with respect to the dispensing of a con-*
 21 *trolled substance shall include the following:*

22 “(A) *Drug Enforcement Administration*
 23 *Registration Number (or other identifying num-*
 24 *ber used in lieu of such Registration Number) of*
 25 *the dispenser.*

1 “(B) *Drug Enforcement Administration*
2 *Registration Number (or other identifying num-*
3 *ber used in lieu of such Registration Number)*
4 *and name of the practitioner who prescribed the*
5 *drug.*

6 “(C) *Name, address, and telephone number*
7 *of the ultimate user or such contact information*
8 *of the ultimate user as the Secretary determines*
9 *appropriate.*

10 “(D) *Identification of the drug by a na-*
11 *tional drug code number.*

12 “(E) *Quantity dispensed.*

13 “(F) *Number of refills ordered.*

14 “(G) *Whether the drug was dispensed as a*
15 *refill of a prescription or as a first-time request.*

16 “(H) *Date of the dispensing.*

17 “(I) *Date of origin of the prescription.*

18 “(4) *The State shall require dispensers to report*
19 *information under this section in accordance with the*
20 *electronic format specified by the Secretary under*
21 *subsection (h), except that the State may waive the re-*
22 *quirement of such format with respect to an indi-*
23 *vidual dispenser that is unable to submit such infor-*
24 *mation by electronic means.*

1 “(e) *DATABASE.—In implementing or improving a*
 2 *controlled substance monitoring program under this section,*
 3 *a State shall comply with the following:*

4 “(1) *The State shall establish and maintain an*
 5 *electronic database containing the information re-*
 6 *ported to the State under subsection (d).*

7 “(2) *The database must be searchable by any*
 8 *field or combination of fields.*

9 “(3) *The State shall include reported informa-*
 10 *tion in the database in a manner consistent with cri-*
 11 *teria established by the Secretary, with appropriate*
 12 *safeguards for ensuring the accuracy and complete-*
 13 *ness of the database.*

14 “(4) *The State shall take appropriate security*
 15 *measures to protect the integrity of, and access to, the*
 16 *database.*

17 “(f) *USE AND DISCLOSURE OF INFORMATION.—*

18 “(1) *IN GENERAL.—Subject to subsection (g), in*
 19 *implementing or improving a controlled substance*
 20 *monitoring program under this section, a State may*
 21 *disclose information from the database established*
 22 *under subsection (e) and, in the case of a request*
 23 *under subsection (f)(1)(D), summary statistics of such*
 24 *information, only in response to a request by—*

1 “(A) a practitioner (or the agent thereof)
2 who certifies, under the procedures determined by
3 the State, that the requested information is for
4 the purpose of providing medical or pharma-
5 ceutical treatment or evaluating the need for
6 such treatment to a bona fide current patient;

7 “(B) any local, State, or Federal law en-
8 forcement, narcotics control, licensure, discipli-
9 nary, or program authority, who certifies, under
10 the procedures determined by the State, that the
11 requested information is related to an individual
12 investigation or proceeding involving the unlaw-
13 ful diversion or misuse of a schedule II, III, or
14 IV substance, and such information will further
15 the purpose of the investigation or assist in the
16 proceeding;

17 “(C) the controlled substance monitoring
18 program of another State or group of States with
19 whom the State has established an interoper-
20 ability agreement;

21 “(D) any agent of the Department of Health
22 and Human Services, a State medicaid pro-
23 gram, a State health department, or the Drug
24 Enforcement Administration who certifies that
25 the requested information is necessary for re-

1 *search to be conducted by such department, pro-*
 2 *gram, or administration, respectively, and the*
 3 *intended purpose of the research is related to a*
 4 *function committed to such department, pro-*
 5 *gram, or administration by law that is not in-*
 6 *vestigative in nature; or*

7 *“(E) an agent of the State agency or entity*
 8 *of another State that is responsible for the estab-*
 9 *lishment and maintenance of that State’s con-*
 10 *trolled substance monitoring program, who cer-*
 11 *tifies that—*

12 *“(i) the State has an application ap-*
 13 *proved under this section; and*

14 *“(ii) the requested information is for*
 15 *the purpose of implementing the State’s*
 16 *controlled substance monitoring program*
 17 *under this section.*

18 *“(2) DRUG DIVERSION.—In consultation with*
 19 *practitioners, dispensers, and other relevant and in-*
 20 *terested stakeholders, a State receiving a grant under*
 21 *subsection (a)—*

22 *“(A) shall establish a program to notify*
 23 *practitioners and dispensers of information that*
 24 *will help identify and prevent the unlawful di-*
 25 *version or misuse of controlled substances; and*

1 “(B) may, to the extent permitted under
 2 State law, notify the appropriate authorities re-
 3 sponsible for carrying out drug diversion inves-
 4 tigations if the State determines that informa-
 5 tion in the database maintained by the State
 6 under subsection (e) indicates an unlawful diver-
 7 sion or abuse of a controlled substance.

8 “(g) *LIMITATIONS.*—In implementing or improving a
 9 controlled substance monitoring program under this section,
 10 a State—

11 “(1) shall limit the information provided pursu-
 12 ant to a valid request under subsection (f)(1) to the
 13 minimum necessary to accomplish the intended pur-
 14 pose of the request; and

15 “(2) shall limit information provided in response
 16 to a request under subsection (f)(1)(D) to nonidentifi-
 17 able information.

18 “(h) *ELECTRONIC FORMAT.*—The Secretary shall
 19 specify a uniform electronic format for the reporting, shar-
 20 ing, and disclosure of information under this section.

21 “(i) *RULES OF CONSTRUCTION.*—

22 “(1) *FUNCTIONS OTHERWISE AUTHORIZED BY*
 23 *LAW.*—Nothing in this section shall be construed to
 24 restrict the ability of any authority, including any
 25 local, State, or Federal law enforcement, narcotics

1 *control, licensure, disciplinary, or program authority,*
 2 *to perform functions otherwise authorized by law.*

3 “(2) *NO PREEMPTION.*—*Nothing in this section*
 4 *shall be construed as preempting any State law, ex-*
 5 *cept that no such law may relieve any person of a re-*
 6 *quirement otherwise applicable under this Act.*

7 “(3) *ADDITIONAL PRIVACY PROTECTIONS.*—*Noth-*
 8 *ing in this section shall be construed as preempting*
 9 *any State from imposing any additional privacy pro-*
 10 *tections.*

11 “(4) *CERTAIN CONFIDENTIALITY REQUIRE-*
 12 *MENTS.*—*Nothing in this section shall be construed as*
 13 *preempting the confidentiality requirements of part 2*
 14 *and part 2a of title 42, Code of Federal Regulations.*

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

18 “(j) *STUDIES AND REPORTS.*—

19 “(1) *IMPLEMENTATION REPORT.*—

20 “(A) *IN GENERAL.*—*Not later than 180*
 21 *days after the date of enactment of this section,*
 22 *the Secretary, based on a review of existing State*
 23 *controlled substance monitoring programs and*
 24 *other relevant information, shall determine*

1 *whether the implementation of such programs*
2 *has had a substantial negative impact on—*

3 “(i) *patient access to treatment, in-*
4 *cluding therapy for pain or controlled sub-*
5 *stance abuse;*

6 “(ii) *pediatric patient access to treat-*
7 *ment; or*

8 “(iii) *patient enrollment in research or*
9 *clinical trials in which, following the pro-*
10 *TOCOL that has been approved by the relevant*
11 *institutional review board for the research*
12 *or clinical trial, the patient has obtained a*
13 *controlled substance from either the sci-*
14 *entific investigator conducting such research*
15 *or clinical trial or the agent thereof.*

16 “(B) *ADDITIONAL CATEGORIES OF EXCLU-*
17 *SION.—If the Secretary determines under sub-*
18 *paragraph (A) that a substantial negative im-*
19 *pact has been demonstrated with regard to one*
20 *or more of the categories of patients described in*
21 *such subparagraph, the Secretary shall identify*
22 *additional appropriate categories of exclusion*
23 *from reporting as authorized under subsection*
24 *(d)(2)(C).*

1 “(2) *PROGRESS REPORT*.—Not later than 3 years
2 *after the date on which funds are first appropriated*
3 *under this section, the Secretary shall—*

4 “(A) *complete a study that—*

5 “(i) *determines the progress of States*
6 *in establishing and implementing controlled*
7 *substance monitoring programs under this*
8 *section;*

9 “(ii) *determines the progress of States*
10 *in achieving interoperability between con-*
11 *trolled substance monitoring programs, in-*
12 *cluding an assessment of technical and legal*
13 *barriers to such activities and recommenda-*
14 *tions for addressing these barriers;*

15 “(iii) *determines the feasibility of im-*
16 *plementing a real-time electronic controlled*
17 *substance monitoring program, including*
18 *the costs associated with establishing such a*
19 *program;*

20 “(iv) *provides an analysis of the pri-*
21 *vacv protections in place for the informa-*
22 *tion reported to the controlled substance*
23 *monitoring program in each State receiving*
24 *a grant for the establishment or operation of*
25 *such program, and any recommendations*

1 *for additional requirements for protection of*
 2 *this information;*

3 “(v) *determines the feasibility of imple-*
 4 *menting technological alternatives to cen-*
 5 *tralized data storage, such as peer-to-peer*
 6 *file sharing or data pointer systems, in con-*
 7 *trolled substance monitoring programs and*
 8 *the potential for such alternatives to en-*
 9 *hance the privacy and security of individ-*
 10 *ually identifiable data; and*

11 “(vi) *evaluates the penalties that*
 12 *States have enacted for the unauthorized use*
 13 *and disclosure of information maintained*
 14 *in the controlled substance monitoring pro-*
 15 *gram, and reports on the criteria used by*
 16 *the Secretary to determine whether such*
 17 *penalties qualify as appropriate pursuant*
 18 *to this section; and*

19 “(B) *submit a report to the Congress on the*
 20 *results of the study.*

21 “(k) *ADVISORY COUNCIL.—*

22 “(1) *ESTABLISHMENT.—A State may establish*
 23 *an advisory council to assist in the establishment, im-*
 24 *plementation, or improvement of a controlled sub-*
 25 *stance monitoring program under this section.*

1 “(2) *LIMITATION.*—A State may not use
2 amounts received under a grant under this section for
3 the operations of an advisory council established
4 under paragraph (1).

5 “(3) *SENSE OF CONGRESS.*—It is the sense of the
6 Congress that, in establishing an advisory council
7 under this subsection, a State should consult with ap-
8 propriate professional boards and other interested
9 parties.

10 “(l) *DEFINITIONS.*—For purposes of this section:

11 “(1) The term ‘bona fide patient’ means an indi-
12 vidual who is a patient of the dispenser or practi-
13 tioner involved.

14 “(2) The term ‘controlled substance’ means a
15 drug that is included in schedule II, III, or IV of sec-
16 tion 202(c) of the Controlled Substance Act.

17 “(3) The term ‘dispense’ means to deliver a con-
18 trolled substance to an ultimate user by, or pursuant
19 to the lawful order of, a practitioner, irrespective of
20 whether the dispenser uses the Internet or other means
21 to effect such delivery.

22 “(4) The term ‘dispenser’ means a physician,
23 pharmacist, or other person that dispenses a con-
24 trolled substance to an ultimate user.

1 “(5) The term ‘interoperability’ with respect to a
2 State controlled substance monitoring program means
3 the ability of the program to electronically share re-
4 ported information, including each of the required re-
5 port components described in subsection (d), with an-
6 other State if the information concerns either the dis-
7 pensing of a controlled substance to an ultimate user
8 who resides in such other State, or the dispensing of
9 a controlled substance prescribed by a practitioner
10 whose principal place of business is located in such
11 other State.

12 “(6) The term ‘nonidentifiable information’
13 means information that does not identify a practi-
14 tioner or an ultimate user and with respect to which
15 there is no reasonable basis to believe that the infor-
16 mation can be used to identify a practitioner or an
17 ultimate user.

18 “(7) The term ‘practitioner’ means a physician,
19 dentist, veterinarian, scientific investigator, phar-
20 macy, hospital, or other person licensed, registered, or
21 otherwise permitted, by the United States or the juris-
22 diction in which he or she practices or does research,
23 to distribute, dispense, conduct research with respect
24 to, administer, or use in teaching or chemical anal-

1 *ysis, a controlled substance in the course of profes-*
 2 *sional practice or research.*

3 “(8) *The term ‘State’ means each of the 50*
 4 *States and the District of Columbia.*

5 “(9) *The term ‘ultimate user’ means a person*
 6 *who has obtained from a dispenser, and who pos-*
 7 *sesses, a controlled substance for his or her own use,*
 8 *for the use of a member of his or her household, or*
 9 *for the use of an animal owned by him or her or by*
 10 *a member of his or her household.*

11 “(m) *AUTHORIZATION OF APPROPRIATIONS.—To*
 12 *carry out this section, there are authorized to be appro-*
 13 *priated—*

14 “(1) *\$15,000,000 for each of fiscal years 2006*
 15 *and 2007; and*

16 “(2) *\$10,000,000 for each of fiscal years 2008,*
 17 *2009, and 2010.”.*

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109TH CONGRESS
1ST Session

S. 518

[Report No. 109-117]

A BILL

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

JULY 29, 2005

Reported with an amendment