

109TH CONGRESS
1ST SESSION

H. R. 1132

IN THE SENATE OF THE UNITED STATES

JULY 28, 2005

Received

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National All Schedules
3 Prescription Electronic Reporting Act of 2005”.

4 **SEC. 2. PURPOSE.**

5 It is the purpose of this Act to—

6 (1) foster the establishment of State-adminis-
7 tered controlled substance monitoring systems in
8 order to ensure that health care providers have ac-
9 cess to the accurate, timely prescription history in-
10 formation that they may use as a tool for the early
11 identification of patients at risk for addiction in
12 order to initiate appropriate medical interventions
13 and avert the tragic personal, family, and commu-
14 nity consequences of untreated addiction; and

15 (2) establish, based on the experiences of exist-
16 ing State controlled substance monitoring programs,
17 a set of best practices to guide the establishment of
18 new State programs and the improvement of existing
19 programs.

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

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

24 **“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-
25 GRAM.**

26 **“(a) GRANTS.—**

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

5 “(A) to establish and implement a State
6 controlled substance monitoring program; or

7 “(B) to make improvements to an existing
8 State controlled substance monitoring program.

9 “(2) DETERMINATION OF AMOUNT.—

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

17 “(B) ADDITIONAL AMOUNTS.—In making
18 payments under a grant under paragraph (1)
19 for a fiscal year, the Secretary shall allocate to
20 each State with an application approved under
21 this section an additional amount which bears
22 the same ratio to the amount appropriated to
23 carry out this section for that fiscal year and
24 remaining after amounts are made available
25 under subparagraph (A) as the number of phar-

1 macies of the State bears to the number of
2 pharmacies of all States with applications ap-
3 proved under this section (as determined by the
4 Secretary), except that the Secretary may ad-
5 just the amount allocated to a State under this
6 subparagraph after taking into consideration
7 the budget cost estimate for the State’s con-
8 trolled substance monitoring program.

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

12 “(b) DEVELOPMENT OF MINIMUM REQUIRE-
13 MENTS.—Prior to awarding a grant under this section,
14 and not later than 6 months after the date on which funds
15 are first appropriated to carry out this section, after seek-
16 ing consultation with States and other interested parties,
17 the Secretary shall, after publishing in the Federal Reg-
18 ister proposed minimum requirements and receiving public
19 comments, establish minimum requirements for criteria to
20 be used by States for purposes of clauses (ii), (v), (vi),
21 and (vii) of subsection (c)(1)(A).

22 “(c) APPLICATION APPROVAL PROCESS.—

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

1 ner, and containing such assurances and information
2 as the Secretary may reasonably require. Each such
3 application shall include—

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

7 “(i) a budget cost estimate for the
8 controlled substance monitoring program
9 to be implemented under the grant;

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

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

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

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

4 “(vi) criteria for access to the data-
5 base, and procedures to ensure that infor-
6 mation in the database is accurate;

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

12 “(viii) penalties for the unauthorized
13 use and disclosure of information main-
14 tained in the State controlled substance
15 monitoring program in violation of applica-
16 ble State law or regulation;

17 “(ix) information on the relevant
18 State laws, policies, and procedures, if any,
19 regarding purging of information from the
20 database; and

21 “(x) assurances of compliance with all
22 other requirements of this section; or

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

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

4 “(ii) a plan for ensuring that the
5 State controlled substance monitoring pro-
6 gram is in compliance with the criteria and
7 penalty requirements described in clauses
8 (ii) through (viii) of subparagraph (A);

9 “(iii) a plan to enable the State con-
10 trolled substance monitoring program to
11 achieve interoperability with at least one
12 other State controlled substance moni-
13 toring program; and

14 “(iv) assurances of compliance with
15 all other requirements of this section or a
16 statement describing why such compliance
17 is not feasible or is contrary to the best in-
18 terests of public health in such State.

19 “(2) STATE LEGISLATION.—As part of an ap-
20 plication under paragraph (1), the Secretary shall
21 require a State to demonstrate that the State has
22 enacted legislation or regulations to permit the im-
23 plementation of the State controlled substance moni-
24 toring program and the imposition of appropriate

1 penalties for the unauthorized use and disclosure of
2 information maintained in such program.

3 “(3) INTEROPERABILITY.—If a State that sub-
4 mits an application under this subsection geographi-
5 cally borders another State that is operating a con-
6 trolled substance monitoring program under sub-
7 section (a)(1) on the date of submission of such ap-
8 plication, and such applicant State has not achieved
9 interoperability for purposes of information sharing
10 between its monitoring program and the monitoring
11 program of such border State, such applicant State
12 shall, as part of the plan under paragraph
13 (1)(B)(iii), describe the manner in which the appli-
14 cant State will achieve interoperability between the
15 monitoring programs of such States.

16 “(4) APPROVAL.—If a State submits an appli-
17 cation in accordance with this subsection, the Sec-
18 retary shall approve such application.

19 “(5) RETURN OF FUNDS.—If the Secretary
20 withdraws approval of a State’s application under
21 this section, or the State chooses to cease to imple-
22 ment or improve a controlled substance monitoring
23 program under this section, a funding agreement for
24 the receipt of a grant under this section is that the
25 State will return to the Secretary an amount which

1 bears the same ratio to the overall grant as the re-
2 maining time period for expending the grant funds
3 bears to the overall time period for expending the
4 grant (as specified by the Secretary at the time of
5 the grant).

6 “(d) REPORTING REQUIREMENTS.—In implementing
7 or improving a controlled substance monitoring program
8 under this section, a State shall comply, or with respect
9 to a State that applies for a grant under subsection
10 (a)(1)(B) submit to the Secretary for approval a state-
11 ment of why such compliance is not feasible or is contrary
12 to the best interests of public health in such State, with
13 the following:

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

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

20 “(A) the direct administration of a con-
21 trolled substance to the body of an ultimate
22 user;

23 “(B) the dispensing of a controlled sub-
24 stance in a quantity limited to an amount ade-

1 quate to treat the ultimate user involved for 48
2 hours or less; or

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

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

10 “(A) Drug Enforcement Administration
11 Registration Number (or other identifying num-
12 ber used in lieu of such Registration Number)
13 of the dispenser.

14 “(B) Drug Enforcement Administration
15 Registration Number (or other identifying num-
16 ber used in lieu of such Registration Number)
17 and name of the practitioner who prescribed the
18 drug.

19 “(C) Name, address, and telephone num-
20 ber of the ultimate user or such contact infor-
21 mation of the ultimate user as the Secretary de-
22 termines appropriate.

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

25 “(E) Quantity dispensed.

1 “(F) Number of refills ordered.

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

4 “(H) Date of the dispensing.

5 “(I) Date of origin of the prescription.

6 “(J) Such other information as may be re-
7 quired by State law to be reported under this
8 subsection.

9 “(4) The State shall require dispensers to re-
10 port information under this section in accordance
11 with the electronic format specified by the Secretary
12 under subsection (h), except that the State may
13 waive the requirement of such format with respect to
14 an individual dispenser that is unable to submit such
15 information by electronic means.

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

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

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

24 “(3) The State shall include reported informa-
25 tion in the database in a manner consistent with cri-

1 teria established by the Secretary, with appropriate
2 safeguards for ensuring the accuracy and complete-
3 ness of the database.

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

7 “(f) USE AND DISCLOSURE OF INFORMATION.—

8 “(1) IN GENERAL.—Subject to subsection (g),
9 in implementing or improving a controlled substance
10 monitoring program under this section, a State may
11 disclose information from the database established
12 under subsection (e) and, in the case of a request
13 under subparagraph (D), summary statistics of such
14 information, only in response to a request by—

15 “(A) a practitioner (or the agent thereof)
16 who certifies, under the procedures determined
17 by the State, that the requested information is
18 for the purpose of providing medical or pharma-
19 ceutical treatment or evaluating the need for
20 such treatment to a bona fide current patient;

21 “(B) any local, State, or Federal law en-
22 forcement, narcotics control, licensure, discipli-
23 nary, or program authority, who certifies, under
24 the procedures determined by the State, that
25 the requested information is related to an indi-

1 vidual investigation or proceeding involving the
2 unlawful diversion or misuse of a schedule II,
3 III, or IV substance, and such information will
4 further the purpose of the investigation or as-
5 sist in the proceeding;

6 “(C) the controlled substance monitoring
7 program of another State or group of States
8 with whom the State has established an inter-
9 operability agreement;

10 “(D) any agent of the Department of
11 Health and Human Services, a State medicaid
12 program, a State health department, or the
13 Drug Enforcement Administration who certifies
14 that the requested information is necessary for
15 research to be conducted by such department,
16 program, or administration, respectively, and
17 the intended purpose of the research is related
18 to a function committed to such department,
19 program, or administration by law that is not
20 investigative in nature; or

21 “(E) an agent of the State agency or enti-
22 ty of another State that is responsible for the
23 establishment and maintenance of that State’s
24 controlled substance monitoring program, who
25 certifies that—

1 “(i) the State has an application ap-
2 proved under this section; and

3 “(ii) the requested information is for
4 the purpose of implementing the State’s
5 controlled substance monitoring program
6 under this section.

7 “(2) DRUG DIVERSION.—In consultation with
8 practitioners, dispensers, and other relevant and in-
9 terested stakeholders, a State receiving a grant
10 under subsection (a)—

11 “(A) shall establish a program to notify
12 practitioners and dispensers of information that
13 will help identify and prevent the unlawful di-
14 version or misuse of controlled substances; and

15 “(B) may, to the extent permitted under
16 State law, notify the appropriate authorities re-
17 sponsible for carrying out drug diversion inves-
18 tigations if the State determines that informa-
19 tion in the database maintained by the State
20 under subsection (e) indicates an unlawful di-
21 version or abuse of a controlled substance.

22 “(g) LIMITATIONS.—In implementing or improving a
23 controlled substance monitoring program under this sec-
24 tion, a State—

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

5 “(2) shall limit information provided in re-
6 sponse to a request under subsection (f)(1)(D) to
7 nonidentifiable information.

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

11 “(i) RULES OF CONSTRUCTION.—

12 “(1) FUNCTIONS OTHERWISE AUTHORIZED BY
13 LAW.—Nothing in this section shall be construed to
14 restrict the ability of any authority, including any
15 local, State, or Federal law enforcement, narcotics
16 control, licensure, disciplinary, or program authority,
17 to perform functions otherwise authorized by law.

18 “(2) NO PREEMPTION.—Nothing in this section
19 shall be construed as preempting any State law, ex-
20 cept that no such law may relieve any person of a
21 requirement otherwise applicable under this Act.

22 “(3) ADDITIONAL PRIVACY PROTECTIONS.—
23 Nothing in this section shall be construed as pre-
24 empting any State from imposing any additional pri-
25 vacy protections.

1 “(4) FEDERAL PRIVACY REQUIREMENTS.—
2 Nothing in this section shall be construed to super-
3 sede any Federal privacy or confidentiality require-
4 ment, including the regulations promulgated under
5 section 264(c) of the Health Insurance Portability
6 and Accountability Act of 1996 (Public Law 104-
7 191; 110 Stat. 2033) and section 543 of the Public
8 Health Service Act.

9 “(5) NO FEDERAL PRIVATE CAUSE OF AC-
10 TION.—Nothing in this section shall be construed to
11 create a Federal private cause of action.

12 “(j) STUDIES AND REPORTS.—

13 “(1) IMPLEMENTATION REPORT.—

14 “(A) IN GENERAL.—Not later than 180
15 days after the date of enactment of this section,
16 the Secretary, based on a review of existing
17 State controlled substance monitoring programs
18 and other relevant information, shall determine
19 whether the implementation of such programs
20 has had a substantial negative impact on—

21 “(i) patient access to treatment, in-
22 cluding therapy for pain or controlled sub-
23 stance abuse;

24 “(ii) pediatric patient access to treat-
25 ment; or

1 “(iii) patient enrollment in research or
2 clinical trials in which, following the pro-
3 tocol that has been approved by the rel-
4 evant institutional review board for the re-
5 search or clinical trial, the patient has ob-
6 tained a controlled substance from either
7 the scientific investigator conducting such
8 research or clinical trial or the agent there-
9 of.

10 “(B) ADDITIONAL CATEGORIES OF EXCLU-
11 SION.—If the Secretary determines under sub-
12 paragraph (A) that a substantial negative im-
13 pact has been demonstrated with regard to one
14 or more of the categories of patients described
15 in such subparagraph, the Secretary shall iden-
16 tify additional appropriate categories of exclu-
17 sion from reporting as authorized under sub-
18 section (d)(2)(C).

19 “(2) PROGRESS REPORT.—Not later than 3
20 years after the date on which funds are first appro-
21 priated under this section, the Secretary shall—

22 “(A) complete a study that—

23 “(i) determines the progress of States
24 in establishing and implementing con-

1 trolled substance monitoring programs
2 under this section;

3 “(ii) provides an analysis of the extent
4 to which the operation of controlled sub-
5 stance monitoring programs have reduced
6 inappropriate use, abuse, or diversion of
7 controlled substances or affected patient
8 access to appropriate pain care in States
9 operating such programs;

10 “(iii) determines the progress of
11 States in achieving interoperability between
12 controlled substance monitoring programs,
13 including an assessment of technical and
14 legal barriers to such activities and rec-
15 ommendations for addressing these bar-
16 riers;

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

22 “(v) provides an analysis of the pri-
23 vacy protections in place for the informa-
24 tion reported to the controlled substance
25 monitoring program in each State receiv-

1 ing a grant for the establishment or oper-
2 ation of such program, and any rec-
3 ommendations for additional requirements
4 for protection of this information;

5 “(vi) determines the feasibility of im-
6 plementing technological alternatives to
7 centralized data storage, such as peer-to-
8 peer file sharing or data pointer systems,
9 in controlled substance monitoring pro-
10 grams and the potential for such alter-
11 natives to enhance the privacy and security
12 of individually identifiable data; and

13 “(vii) evaluates the penalties that
14 States have enacted for the unauthorized
15 use and disclosure of information main-
16 tained in the controlled substance moni-
17 toring program, and reports on the criteria
18 used by the Secretary to determine wheth-
19 er such penalties qualify as appropriate
20 pursuant to this section; and

21 “(B) submit a report to the Congress on
22 the results of the study.

23 “(k) PREFERENCE.—Beginning 3 years after the
24 date on which funds are first appropriated to carry out
25 this section, the Secretary, in awarding any competitive

1 grant that is related to drug abuse (as determined by the
2 Secretary) and for which only States are eligible to apply,
3 shall give preference to any State with an application ap-
4 proved under this section. The Secretary shall have the
5 discretion to apply such preference to States with existing
6 controlled substance monitoring programs that meet min-
7 imum requirements under this section or to States that
8 put forth a good faith effort to meet those requirements
9 (as determined by the Secretary).

10 “(1) ADVISORY COUNCIL.—

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

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

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

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

1 “(1) The term ‘bona fide patient’ means an in-
2 dividual who is a patient of the practitioner involved.

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

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

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

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

1 “(6) The term ‘nonidentifiable information’
2 means information that does not identify a practi-
3 tioner, dispenser, or an ultimate user and with re-
4 spect to which there is no reasonable basis to believe
5 that the information can be used to identify a practi-
6 tioner, dispenser, or an ultimate user.

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

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

18 “(9) The term ‘ultimate user’ means a person
19 who has obtained from a dispenser, and who pos-
20 sesses, a controlled substance for his or her own use,
21 for the use of a member of his or her household, or
22 for the use of an animal owned by him or her or by
23 a member of his or her household.

1 “(n) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there are authorized to be appro-
3 priated—

4 “(1) \$15,000,000 for each of fiscal years 2006
5 and 2007; and

6 “(2) \$10,000,000 for each of fiscal years 2008,
7 2009, and 2010.”.

Passed the House of Representatives July 27, 2005.

Attest:

JEFF TRANDAHL,

Clerk.