

108TH CONGRESS
2^D SESSION

H. R. 3015

AN ACT

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

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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 2004”.

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

5 Part P of title III of the Public Health Service Act
6 (42 U.S.C. 280g et seq.) is amended by adding after sec-
7 tion 399N the following:

8 **“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-
9 GRAM.**

10 “(a) FORMULA GRANTS.—

11 “(1) IN GENERAL.—Each fiscal year, the Sec-
12 retary shall make a payment to each State with an
13 application approved under this section for the pur-
14 pose of establishing and implementing a controlled
15 substance monitoring program under this section.

16 “(2) DETERMINATION OF AMOUNT.—In making
17 payments under paragraph (1) for a fiscal year, the
18 Secretary shall allocate to each State with an appli-
19 cation approved under this section an amount which
20 bears the same ratio to the amount appropriated to
21 carry out this section for that fiscal year as the
22 number of pharmacies of the State bears to the
23 number of pharmacies of all States with applications
24 approved under this section (as determined by the
25 Secretary), except that the Secretary may adjust the
26 amount allocated to a State under this paragraph

1 after taking into consideration the budget cost esti-
2 mate for the State’s controlled substance monitoring
3 program.

4 “(b) APPLICATION APPROVAL PROCESS.—

5 “(1) IN GENERAL.—To seek a grant under this
6 section, a State shall submit an application at such
7 time, in such manner, and containing such assur-
8 ances and information as the Secretary may reason-
9 ably require. Each such application shall include—

10 “(A) a budget cost estimate for the State’s
11 controlled substance monitoring program;

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

17 “(C) proposed standards for meeting the
18 uniform electronic format requirement of sub-
19 section (g);

20 “(D) proposed standards for availability of
21 information and limitation on access to pro-
22 gram personnel;

23 “(E) proposed standards for access to the
24 database, and procedures to ensure database
25 accuracy;

1 “(F) proposed standards for redisclosure
2 of information;

3 “(G) proposed penalties for illegal redisclo-
4 sure of information; and

5 “(H) assurances of compliance with all
6 other requirements of this section.

7 “(2) APPROVAL OR DISAPPROVAL.—Not later
8 than 90 days after the submission by a State of an
9 application under paragraph (1), the Secretary shall
10 approve or disapprove the application. The Secretary
11 shall approve the application if the State dem-
12 onstrates to the Secretary that the State will estab-
13 lish and implement or operate a controlled substance
14 monitoring program in accordance with this section.

15 “(3) WITHDRAWAL OF AUTHORIZATION.—If a
16 State fails to implement a controlled substance mon-
17 itoring program in accordance with this section—

18 “(A) the Secretary shall give notice of the
19 failure to the State; and

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

24 “(4) VOLUNTARY DISCONTINUANCE.—A fund-
25 ing agreement for the receipt of a payment under

1 this section is that the State involved will give a rea-
2 sonable period of notice to the Secretary before ceas-
3 ing to implement or operate a controlled substance
4 monitoring program under this section. The Sec-
5 retary shall determine the period of notice that is
6 reasonable for purposes of this paragraph.

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

19 “(c) REPORTING REQUIREMENTS.—In implementing
20 a controlled substance monitoring program under this sec-
21 tion, a State shall comply with the following:

22 “(1) The State shall require dispensers to re-
23 port to such State each dispensing in the State of
24 a controlled substance to an ultimate user or re-

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

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

5 “(A) the direct administration of a con-
6 trolled substance to the body of an ultimate
7 user or research subject;

8 “(B) the dispensing of a controlled sub-
9 stance in a quantity limited to an amount ade-
10 quate to treat the ultimate user or research
11 subject involved for 48 hours or less; or

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

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

19 “(A) Drug Enforcement Administration
20 Registration Number of the dispenser.

21 “(B) Drug Enforcement Administration
22 Registration Number and name of the practi-
23 tioner who prescribed the drug.

24 “(C) Name, address, and telephone num-
25 ber of the ultimate user or research subject.

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

3 “(E) Quantity dispensed.

4 “(F) Estimated number of days for which
5 such quantity should last.

6 “(G) Number of refills ordered.

7 “(H) Whether the drug was dispensed as
8 a refill of a prescription or as a first-time re-
9 quest.

10 “(I) Date of the dispensing.

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

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

18 “(5) The State shall automatically share infor-
19 mation reported under this subsection with another
20 State with an application approved under this sec-
21 tion if the information concerns—

22 “(A) the dispensing of a controlled sub-
23 stance to an ultimate user or research subject
24 who resides in such other State; or

1 “(B) the dispensing of a controlled sub-
2 stance prescribed by a practitioner whose prin-
3 cipal place of business is located in such other
4 State.

5 “(6) The State may notify the appropriate au-
6 thorities responsible for drug diversion investigation
7 if information in the database maintained by the
8 State under subsection (d) indicates an unlawful di-
9 version or misuse of a controlled substance.

10 “(d) DATABASE.—In implementing a controlled sub-
11 stance monitoring program under this section, a State
12 shall comply with the following:

13 “(1) The State shall establish and maintain an
14 electronic database containing the information re-
15 ported to the State under subsection (c).

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

18 “(3) The State shall include reported informa-
19 tion in the database at such time and in such man-
20 ner as the Secretary determines appropriate, with
21 appropriate safeguards for ensuring the accuracy
22 and completeness of the database.

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

1 “(e) PROVISION OF INFORMATION.—Subject to sub-
2 section (f), in implementing a controlled substance moni-
3 toring program under this section, a State may provide
4 information from the database established under sub-
5 section (d) and, in the case of a request under paragraph
6 (3), summary statistics of such information, in response
7 to a request by—

8 “(1) a practitioner (or the agent thereof) who
9 certifies, under the procedures determined by the
10 State, that the requested information is for the pur-
11 pose of providing medical or pharmaceutical treat-
12 ment or evaluating the need for such treatment to
13 a bona fide current patient;

14 “(2) any local, State, or Federal law enforce-
15 ment, narcotics control, licensure, disciplinary, or
16 program authority, who certifies, under the proce-
17 dures determined by the State, that the requested
18 information is related to an individual investigation
19 or proceeding involving the unlawful diversion or
20 misuse of a schedule II, III, or IV substance, and
21 such information will further the purpose of the in-
22 vestigation or assist in the proceeding;

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

1 Administration who certifies that the requested in-
2 formation is necessary for research to be conducted
3 by such department, program, or administration, re-
4 spectively, and the intended purpose of the research
5 is related to a function committed to such depart-
6 ment, program, or administration by law that is not
7 investigative in nature; or

8 “(4) any agent of another State, who certifies
9 that the State has an application approved under
10 this section and the requested information is for the
11 purpose of implementing the State’s controlled sub-
12 stance monitoring program under this section.

13 “(f) LIMITATIONS.—In implementing a controlled
14 substance monitoring program under this section, a
15 State—

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

20 “(2) shall not provide any individually identifi-
21 able information in response to a request under sub-
22 section (e)(3).

23 “(g) ELECTRONIC FORMAT.—The Secretary shall
24 specify a uniform electronic format for the reporting, shar-
25 ing, and provision of information under this section.

1 “(h) RULES OF CONSTRUCTION.—

2 “(1) FUNCTIONS OTHERWISE AUTHORIZED BY
3 LAW.—Nothing in this section shall be construed to
4 restrict the ability of any authority, including any
5 local, State, or Federal law enforcement, narcotics
6 control, licensure, disciplinary, or program authority,
7 to perform functions otherwise authorized by law.

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

12 “(3) ADDITIONAL PRIVACY PROTECTIONS.—
13 Nothing in this section shall be construed as pre-
14 empting any State from imposing any additional pri-
15 vacy protections.

16 “(4) CERTAIN CONFIDENTIALITY REQUIRE-
17 MENTS.—Nothing in this section shall be construed
18 as superceding the confidentiality requirements of
19 programs defined by and subject to part 2 of title
20 42, Code of Federal Regulations.

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

24 “(i) RELATION TO HIPAA.—Except to the extent in-
25 consistent with this section, the provision of information

1 pursuant to subsection (c)(5), (c)(6), or (e) and the subse-
2 quent transfer of such information are subject to any re-
3 quirement that would otherwise apply under the regula-
4 tions promulgated pursuant to section 264(c) of the
5 Health Insurance Portability and Accountability Act of
6 1996.

7 “(j) PREFERENCE.—Beginning January 1, 2007, the
8 Secretary, in awarding any competitive grant that is re-
9 lated to drug abuse (as determined by the Secretary) to
10 a State, shall give preference to any State with an applica-
11 tion approved under this section.

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

14 “(1) complete a study that—

15 “(A) determines the progress of States in
16 establishing and implementing controlled sub-
17 stance monitoring programs under this section;

18 “(B) determines the feasibility of imple-
19 menting a real-time electronic controlled sub-
20 stance monitoring program, including the costs
21 associated with establishing such a program;
22 and

23 “(C) provides an analysis of the privacy
24 protections in place for the information re-
25 ported to the controlled substance monitoring

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

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

12 “(l) ADVISORY COUNCIL.—

13 “(1) ESTABLISHMENT.—A State may establish
14 an advisory council to assist in the establishment
15 and implementation of a controlled substance moni-
16 toring 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 or research
6 subject by, or pursuant to the lawful order of, a
7 practitioner, irrespective of whether the dispenser
8 uses the Internet or other means to effect such deliv-
9 ery.

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

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

23 “(6) The term ‘State’ means each of the 50
24 States and the District of Columbia.

1 “(7) The term ‘ultimate user’ means a person
2 who has lawfully obtained, and who possesses, a con-
3 trolled substance for his or her own use, for the use
4 of a member of his or her household, or for the use
5 of an animal owned by him or her or by a member
6 of his or her household.

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

10 “(1) \$25,000,000 for each of fiscal years 2006
11 and 2007; and

12 “(2) \$15,000,000 for each of fiscal years 2008,
13 2009, and 2010.”.

 Passed the House of Representatives October 5,
2004.

Attest:

Clerk.