

108TH CONGRESS
2D SESSION

S. 2288

To amend the Public Health Service Act to assist States in establishing, maintaining, and improving systems to reduce the diversion and abuse of prescription drugs.

IN THE SENATE OF THE UNITED STATES

APRIL 6, 2004

Ms. COLLINS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to assist States in establishing, maintaining, and improving systems to reduce the diversion and abuse of prescription drugs.

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 “Prescription Drug
5 Stewardship Act”.

6 **SEC. 2. PRESCRIPTION DRUG STEWARDSHIP.**

7 Title V of the Public Health Service Act (42 U.S.C.
8 290aa et seq.) is amended by adding at the end the fol-
9 lowing:

1 **“PART J—PRESCRIPTION DRUG STEWARDSHIP**

2 **“SEC. 596. PURPOSE.**

3 “It is the purpose of this part to provide grants to
4 assist States in establishing, maintaining, and improving
5 systems to—

6 “(1) track the distribution of prescription drugs
7 from the prescribing health care providers to the
8 pharmacy and, finally, to the patient;

9 “(2) provide continuing education programs for
10 health care providers concerning issues pertaining to
11 prescription drug abuse among patients and col-
12 leagues; and

13 “(3) provide education programs for the public
14 on the problem of prescription drug diversion and
15 abuse.

16 **“SEC. 596A. GRANT AUTHORITY.**

17 “The Secretary, acting through the Administrator of
18 the Substance Abuse and Mental Health Services Admin-
19 istration, shall establish a program to award competitive
20 grants, payable over 3 years, to States under sections
21 596B through 596D to establish, maintain, and improve
22 prescription drug monitoring and education. A State may
23 receive a grant under one or more of such sections.

24 **“SEC. 596B. PRESCRIPTION DRUG MONITORING GRANTS.**

25 “(a) ELIGIBILITY.—To be eligible for a grant under
26 this section, a State shall—

1 “(1) have in effect, or have enacted within 1
2 year of receiving such a grant, laws or policies meet-
3 ing the requirements of subsection (c) that require
4 the periodic and regular reporting by pharmacies of
5 data on prescriptions filled;

6 “(2) prepare and submit to the Secretary an
7 application in accordance with subsection (b); and

8 “(3) provide matching funds in accordance with
9 subsection (f).

10 “(b) APPLICATION.—An application under this sub-
11 section shall include—

12 “(1) a description of the system that the State
13 has established, or intends to establish, to ensure the
14 effective monitoring of prescription drugs from pre-
15 scribing health care provider to pharmacy to patient;

16 “(2) a description of the process by which the
17 State has established, or intends to establish, the
18 system described in paragraph (1) that includes the
19 names of the participants, the timelines for such es-
20 tablishment, and any previous or ongoing efforts re-
21 lated to the establishment of a statewide system to
22 reduce the diversion and abuse of prescription drugs;

23 “(3) a description of the entity that is the des-
24 ignated State authority to collect and safeguard the
25 information collected by the monitoring system;

1 “(4) an estimate, based upon the best available
2 data, of the extent of prescription drug diversion
3 and abuse in the State, of any trends relating to
4 such diversion and abuse, of the types of prescrip-
5 tion drugs diverted, and of any local or regional di-
6 version and abuse patterns that have been detected;

7 “(5) a description of existing systems in the
8 State used to track the distribution of prescription
9 drugs, including a description of how suspected
10 cases of prescription fraud by health care providers,
11 pharmacies, and patients are investigated and how
12 data on the outcome of those investigations is pro-
13 vided to the system;

14 “(6) a description of the current status of inter-
15 agency collaboration among the State’s medical and
16 pharmacy oversight boards, law-enforcement offi-
17 cials, and substance-abuse authorities that dem-
18 onstrates a foundation on which the State can build
19 a collaborative system that fully protects patient
20 confidentiality;

21 “(7) a description of the current status of infor-
22 mation-sharing regarding prescribing practices with
23 other States and of efforts made to improve such in-
24 formation-sharing;

1 “(8) a description of the existing, or planned,
2 protections to ensure that the prescription moni-
3 toring program does not restrict access to drugs by
4 legitimate patients;

5 “(9) a description of the plan of the State for
6 financing the monitoring system at the conclusion of
7 the 3-year grant period;

8 “(10) a description of the source of the State
9 matching funds required under subsection (e); and

10 “(11) any other information determined appro-
11 priate by the Secretary.

12 “(c) REQUIRED STATE LAW OR POLICIES.—A State
13 law or policy meets the requirements of this subsection
14 if such law or policy—

15 “(1) is developed by a collaborative process that
16 is conducted by a commission of stakeholders, in-
17 cluding representatives of the public, health care
18 providers, pharmacists, law enforcement officials,
19 substance-abuse treatment providers, and others de-
20 termined appropriate by the Secretary;

21 “(2) ensures that the handling of information
22 collected under the law or policy is used in compli-
23 ance with the regulations promulgated under section
24 264(c) of the Health Insurance Portability and Ac-
25 countability Act of 1996;

1 “(3) requires that on a regular basis, each
 2 pharmacy in the State report to the State agency
 3 designated under paragraph (3) information on each
 4 prescription filled by the agency, including—

5 “(A) the identity of the prescribing health
 6 care provider;

7 “(B) the identity of the patient;

8 “(C) the drug prescribed; and

9 “(D) the amount of drug prescribed;

10 “(4) ensures that the information provided
 11 under paragraph (3) shall—

12 “(A) be available, upon request, to the
 13 health care provider and patient involved; and

14 “(B) be used only in compliance with the
 15 confidentiality guidelines contained in the regu-
 16 lations promulgated under section 264(c) of the
 17 Health Insurance Portability and Accountability
 18 Act of 1996; and

19 “(5) complies with regulations promulgated by
 20 the Secretary concerning the reporting of informa-
 21 tion concerning activities under a grant under this
 22 section activities during the period of the grant and
 23 at the conclusion of grant funding.

24 “(d) PRIORITY.—In awarding grants under this sec-
 25 tion, the Secretary shall give priority to those States that

1 have in effect, or that enact within 1 year of receiving
2 such a grant, a law—

3 “(1) providing for a prescription-monitoring
4 system that is based upon the model created by the
5 National Association of State Controlled Substance
6 Authorities; and

7 “(2) that requires that Internet pharmacies be
8 licensed in the State and participate in the moni-
9 toring program.

10 “(e) USE OF FUNDS.—Amounts awarded under a
11 grant under this section shall be used by the State for
12 the purposes of establishing, maintaining, and improving
13 a prescription monitoring system, to ensure the account-
14 ability of such system, and to evaluate the performance
15 of such system.

16 “(f) REQUIRED STATE MATCH.—To be eligible to re-
17 ceive a grant under this section a State shall agree that,
18 with respect to the costs to be incurred by the State in
19 carrying out the activities for which the grant was award-
20 ed, the State will make available (in cash or in kind) non-
21 Federal contributions toward such costs in an amount
22 equal to—

23 “(1) for the first fiscal year of payments under
24 the grant, not less than 20 percent of such costs (\$2

1 for each \$10 of Federal funds provided in the
 2 grant);

3 “(2) for the second fiscal year of payments
 4 under the grant, not less than 40 percent of such
 5 costs (\$4 for each \$10 of Federal funds provided in
 6 the grant); and

7 “(3) for the third fiscal year of payments under
 8 the grant, not less than 60 percent of such costs (\$6
 9 for each \$10 of Federal funds provided in the
 10 grant).

11 **“SEC. 596C. HEALTH CARE PROVIDER MENTORING GRANTS.**

12 “(a) PURPOSE.—The purpose of grants awarded
 13 under this section is to assist States in developing and
 14 implementing health care provider education and training
 15 programs to increase awareness among providers of issues
 16 pertaining to prescription-drug diversion and abuse by pa-
 17 tients and colleagues.

18 “(b) ELIGIBILITY.—To be eligible for a grant under
 19 this section, a State shall—

20 “(1) have in effect, or implement within 1 year
 21 of receiving such a grant, a program that meets the
 22 requirements of subsection (d) that provides edu-
 23 cation and training to health care providers con-
 24 cerning prescription-drug diversion and abuse by pa-
 25 tients and colleagues;

1 “(2) prepare and submit to the Secretary an
2 application in accordance with subsection (c); and

3 “(3) provide matching funds in accordance with
4 subsection (g).

5 “(c) APPLICATION.—An application under this sub-
6 section shall include—

7 “(1) a description of the education and training
8 programs of the type described in subsection (d)
9 that the State has or intends to develop;

10 “(2) a description of the collaborative effort by
11 individual health care providers and pharmacists,
12 medical, nursing and pharmacy associations, edu-
13 cational institutions, the State substance abuse au-
14 thority, and other relevant entities to develop the
15 education and training plan;

16 “(3) a description of the process by which men-
17 tors under the education and training plan will be
18 recruited, selected, and trained;

19 “(4) a description of the curriculum developed
20 by the collaborative effort and of the methods that
21 mentors will use to deliver it to colleagues, such as
22 one-on-one or group sessions, seminars, or grand
23 rounds;

24 “(5) a description of the compensation, if any,
25 that will be provided to mentors under the plan;

1 “(6) a description of the collaboration with
2 State medical, nursing, and pharmacy associations
3 that will result in the awarding of continuing edu-
4 cation units to participants in activities under the
5 plan;

6 “(7) a description of the current status of pro-
7 grams, either conducted by the State or by profes-
8 sional associations, to educate health care providers
9 on drug-abuse issues;

10 “(8) a description of the plan of the State for
11 financing the education and training activities under
12 this section at the conclusion of the 3-year grant pe-
13 riod;

14 “(9) a description of the source of the State
15 matching funds required under subsection (f);

16 “(10) a description of the entity that will ad-
17 minister the program, which may include the State
18 substance abuse authority, a State medical, phar-
19 macy or nursing association, an educational institu-
20 tion, or any other entity deemed appropriate by the
21 Secretary; and

22 “(11) any other information determined appro-
23 priate by the Secretary.

1 “(d) STATE EDUCATION AND TRAINING PROGRAM.—

2 An education and training program meets the require-
3 ments of this subsection if such program—

4 “(1) is designed to provide willing health care
5 providers and pharmacists with specialized education
6 and training concerning issues including recognizing
7 drug-seeking behavior and addiction or dependency
8 among patients and colleagues, trends in drug
9 abuse, and current research on drug side effects and
10 interactions;

11 “(2) is developed through collaboration among
12 substance-abuse, education, medical, nursing, phar-
13 macy, and other relevant professionals;

14 “(3) ensures that information is provided in
15 compliance with the confidentiality guidelines con-
16 tained in the regulations promulgated under section
17 264(c) of the Health Insurance Portability and Ac-
18 countability Act of 1996; and

19 “(4) complies with regulations to be promul-
20 gated by the Secretary of the Department of Health
21 and Human Services concerning reporting require-
22 ments under the program both during the period of
23 the grant and upon the termination of grant fund-
24 ing.

1 “(e) PRIORITY.—In awarding grants under this sec-
2 tion, the Secretary shall give priority to those States that,
3 with respect to activities under the education and training
4 program under this section—

5 “(1) have a collaborative body of stakeholders
6 to review the operations and effectiveness of the pro-
7 gram on an ongoing basis and to make adjustments
8 to the program as necessary;

9 “(2) ensure that the pool of mentors includes
10 adequate representation by health care providers
11 from rural, inner city, and other at-risk regions; and

12 “(3) ensure that the mentoring efforts include
13 rural, inner city, and other at-risk communities.

14 “(f) USE OF FUNDS.—Amounts awarded under a
15 grant under this section shall be used by the State for
16 the purposes of establishing and operating a program to
17 mentor health care providers on issues relating to pre-
18 scription drug diversion and abuse, of ensuring its ac-
19 countability, and of evaluating its performance.

20 “(g) REQUIRED STATE MATCH.—To be eligible to re-
21 ceive a grant under this section a State shall agree that,
22 with respect to the costs to be incurred by the State in
23 carrying out the activities for which the grant was award-
24 ed, the State will make available (in cash or in kind) non-

1 Federal contributions toward such costs in an amount
2 equal to—

3 “(1) for the first fiscal year of payments under
4 the grant, not less than 20 percent of such costs (\$2
5 for each \$10 of Federal funds provided in the
6 grant);

7 “(2) for the second fiscal year of payments
8 under the grant, not less than 40 percent of such
9 costs (\$4 for each \$10 of Federal funds provided in
10 the grant); and

11 “(3) for the third fiscal year of payments under
12 the grant, not less than 60 percent of such costs (\$6
13 for each \$10 of Federal funds provided in the
14 grant).

15 **“SEC. 596D. PUBLIC EDUCATION GRANTS.**

16 “(a) PURPOSE.—The purpose of grants awarded
17 under this section is to assist States in developing and
18 implementing programs to increase public awareness of
19 the problem of prescription-drug diversion and abuse.

20 “(b) ELIGIBILITY.—To be eligible for a grant under
21 this section, a State shall—

22 “(1) have in effect, or implement within 1 year
23 of receiving such a grant, a program that meets the
24 requirements of subsection (d) and that provides
25 public education relating to prescription drug diver-

1 sion and abuse and the potential for addiction, de-
2 pendency, and undesirable health outcomes;

3 “(2) prepare and submit to the Secretary an
4 application in accordance with subsection (c); and

5 “(3) provide matching funds in accordance with
6 subsection (g).

7 “(c) APPLICATION.—An application under this sub-
8 section shall include—

9 “(1) a description of the education program
10 that the State is implementing, or intends to imple-
11 ment, to increase public awareness of the problems
12 associated with prescription drug diversion and
13 abuse, including information on the various popu-
14 lation groups that are or will be targeted under the
15 program and the educational methods that are or
16 will be employed for each such population group;

17 “(2) a description of the current status of pre-
18 scription drug diversion and abuse in the state and
19 current efforts to curtail it;

20 “(3) a description of the methods by which the
21 effectiveness of the program under this section will
22 be measured;

23 “(4) a description of the State agency or non-
24 profit organization that will administer the program
25 funded under this section;

1 “(5) a description of the collaborative effort
2 that was used to develop the program;

3 “(6) a description of the plan of the State for
4 financing the program under this section at the con-
5 clusion of the 3-year grant period;

6 “(7) a description of the source of the State
7 matching funds required under subsection (f); and

8 “(8) any other information determined appro-
9 priate by the Secretary.

10 “(d) STATE PUBLIC EDUCATION PROGRAM.—A pub-
11 lic education program meets the requirements of this sub-
12 section if such program is developed through collaboration
13 among substance-abuse authorities, law-enforcement, edu-
14 cation, and health care entities, members of the public,
15 and other relevant entities;

16 “(e) PRIORITY.—In awarding grants under this sec-
17 tion, the Secretary shall give priority to those States that,
18 with respect to activities under the program under this
19 section—

20 “(1) have a collaborative body of stakeholders
21 to review the operations and effectiveness of the pro-
22 gram on an on-going basis and to make adjustments
23 to the program as necessary; and

24 “(2) ensure that the educational efforts include
25 rural, inner city, and other at-risk communities.

1 “(f) USE OF FUNDS.—Amounts awarded under a
2 grant under this section shall be used by the State for
3 the purposes of establishing and operating a program to
4 increase public awareness of the problem of prescription
5 drug diversion and abuse.

6 “(g) REQUIRED STATE MATCH.—To be eligible to re-
7 ceive a grant under this section a State shall agree that,
8 with respect to the costs to be incurred by the State in
9 carrying out the activities for which the grant was award-
10 ed, the State will make available (in cash or in kind) non-
11 Federal contributions toward such costs in an amount
12 equal to—

13 “(1) for the first fiscal year of payments under
14 the grant, not less than 20 percent of such costs (\$2
15 for each \$10 of Federal funds provided in the
16 grant);

17 “(2) for the second fiscal year of payments
18 under the grant, not less than 40 percent of such
19 costs (\$4 for each \$10 of Federal funds provided in
20 the grant); and

21 “(3) for the third fiscal year of payments under
22 the grant, not less than 60 percent of such costs (\$6
23 for each \$10 of Federal funds provided in the
24 grant).

1 **“SEC. 596E. REGULATIONS AND EVALUATION.**

2 “(a) REGULATIONS.—The Secretary is authorized to
3 promulgate regulations as determined necessary to carry
4 out the purposes of the part.

5 “(b) EVALUATION.—Not later than 2 years after the
6 date of enactment of this part, the General Accounting
7 Office shall conduct a study and submit a report to Con-
8 gress concerning how the States have used the amounts
9 provided under this part and whether such activities have
10 been effective in reducing the diversion and abuse of pre-
11 scription drugs.

12 **“SEC. 596F. AUTHORIZATION OF APPROPRIATIONS.**

13 “‘There is authorized to be appropriated to carry out
14 this part, \$20,000,000 for each of fiscal years 2005
15 through 2007.’”.

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