

110TH CONGRESS
2D SESSION

S. 3396

To amend the Public Health Service Act to provide grants or contracts for prescription drug education and outreach for healthcare providers and their patients.

IN THE SENATE OF THE UNITED STATES

JULY 31, 2008

Mr. KOHL (for himself, Mr. DURBIN, Mr. KENNEDY, and Mr. CASEY) 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 provide grants or contracts for prescription drug education and outreach for healthcare providers and their patients.

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 “Independent Drug
5 Education and Outreach Act of 2008”.

6 **SEC. 2. PRESCRIPTION DRUG EDUCATION AND OUTREACH.**

7 Part A of title IX of the Public Health Service Act
8 (42 U.S.C. 299 et seq.) is amended by adding at the end
9 the following:

1 **“SEC. 904. PRESCRIPTION DRUG EDUCATION AND OUT-**
2 **REACH.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director, shall establish a program to award grants
5 or contracts—

6 “(1) under subsection (b) for the development
7 and production of educational materials concerning
8 the evidence available on the relative safety, relative
9 effectiveness, and relative cost of prescription drugs,
10 non-prescription drugs, and non-drug interventions
11 for treating selected conditions, for distribution to
12 healthcare providers who prescribe such drugs and
13 their patients; and

14 “(2) under subsection (c) for the development
15 and implementation of a program to appropriately
16 train and deploy health professionals to educate phy-
17 sicians and other drug prescribers concerning the
18 relative safety, relative effectiveness, and relative
19 cost of prescription drugs, non-prescription drugs,
20 and non-drug interventions for treating selected con-
21 ditions.

22 “(b) EDUCATIONAL MATERIAL GRANTS OR CON-
23 TRACTS.—

24 “(1) IN GENERAL.—The Secretary, acting
25 through the Director, shall award grants or con-
26 tracts to eligible entities for the development and

1 production of educational materials concerning the
 2 evidence available on the relative safety, relative ef-
 3 fectiveness, and relative cost of prescription drugs,
 4 non-prescription drugs, and non-drug interventions
 5 for treating selected conditions, for presentation to
 6 healthcare providers who prescribe such drugs and
 7 their patients.

8 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
 9 ceive a grant or contract under paragraph (1) an en-
 10 tity shall—

11 “(A) be a non-profit or governmental enti-
 12 ty that is able to demonstrate clinical expertise,
 13 including—

14 “(i) a medical school;

15 “(ii) an academic medical center;

16 “(iii) a school of pharmacy;

17 “(iv) a medical society;

18 “(v) a pharmacist society;

19 “(vi) a research institute; and

20 “(vii) any other entity determined ap-
 21 propriate by the Secretary;

22 “(B) receive no support from any entity
 23 that manufactures products used to treat the
 24 medical conditions discussed, or from any orga-
 25 nization funded by such entities, during the pe-

riod beginning 1 year prior to the submission of
an application under this paragraph and ending
1 year after the date on which the grant or con-
tract is received; and

“(C) submit to the Secretary an applica-
tion at such time, in such manner, and con-
taining such information as the Secretary may
require, including—

“(i) information on the conditions for
which the entity will develop and produce
educational materials using grant or con-
tract funds; and

“(ii) a plan for ensuring the effective-
ness of such education materials and for
interacting with entities receiving grants or
contracts under subsection (c).

“(3) CRITERIA FOR AWARDING GRANTS OR
CONTRACTS.—In evaluating grant or contract appli-
cations received under this subsection, the Secretary
shall take into consideration—

“(A) the capacity of the entities to perform
the activities described in paragraph (4);

“(B) the conditions that the educational
materials involved will relate to, with a pref-
erence for minimizing redundancy; and

1 “(C) the quality of the proposed edu-
2 cational materials involved, including—

3 “(i) whether materials are based upon
4 peer-reviewed sources or based upon sci-
5 entific research which conforms to the ac-
6 cepted standards of experimental design,
7 data collection, analysis, and interpreta-
8 tion;

9 “(ii) the likelihood that the materials
10 will accurately reflect the comprehensive
11 body of available evidence that is accepted
12 within the practice of medicine; and

13 “(iii) the adequacy of the methods to
14 be used to analyze the studies proposed to
15 be relied upon.

16 “(4) USE OF FUNDS.—An entity shall use
17 amounts received under a grant or contract under
18 this subsection to—

19 “(A) develop educational materials of the
20 type described in paragraph (1), including
21 monographs, brochures, readily available ref-
22 erence cards, handouts for patients, and other
23 materials in either written or electronic formats
24 (including electronic formats compatible with e-

prescribing) determined appropriate by the Secretary;

“(B) conduct tests concerning the effectiveness of such educational materials with healthcare providers and their patients; and

“(C) prepare and submit to the Director the educational materials by condition, and a report that provides evidence supporting the accuracy of the information and findings in the educational materials, including studies relied upon to prepare such materials, a description of the methods used to analyze those studies, and any studies with conflicting findings that were not included in the educational materials.

“(5) REVIEW OF EDUCATIONAL MATERIALS.—

“(A) IN GENERAL.—The Director shall review and approve proposed educational materials submitted under paragraph (4)(C) within 90 days of the receipt of such materials.

“(B) CLEARANCE OF EDUCATIONAL MATERIALS.—With respect to educational materials that have been reviewed and approved by the Director, the Secretary shall permit the grantee or contractor involved to include on such educational materials the following statement:

1 ‘These materials were compiled under a grant
2 issued by the Department of Health and
3 Human Services.’.

4 “(C) UPDATE OF MATERIALS.—As needed,
5 but not later than 2 years after the date on
6 which the educational materials were approved
7 by the Director, the grantee or contractor in-
8 volved shall submit updated materials to the Di-
9 rector, including the studies used to develop
10 such updates.

11 “(6) AVAILABILITY.—The Director shall ensure
12 that educational materials and reports developed
13 under a grant or contract under this subsection shall
14 be made publically available and accessible, including
15 through the Internet website of the Agency.

16 “(c) PRESCRIBER EDUCATION AND OUTREACH PRO-
17 GRAM.—

18 “(1) IN GENERAL.—The Secretary, acting
19 through the Director, shall award 10 grants or con-
20 tracts to eligible entities for the development and im-
21 plementation of programs to appropriately train and
22 deploy healthcare professionals to educate physicians
23 and other drug prescribers concerning the relative
24 safety, relative effectiveness, and relative cost of pre-
25 scription drugs and their alternatives as described in

subsection (a)(2), and to distribute the educational materials developed under subsection (b) to physicians and other drug prescribers.

“(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant or contract under paragraph (1) an entity shall—

“(A) be—

“(i) a public entity, including a State or county;

“(ii) a non-profit private entity;

“(iii) a partnership between a public entity and a non-profit private entity; or

“(iv) an academic institution;

“(B) receive no support from any entity that manufactures products used to treat the medical conditions discussed, or from any organization funded by such entities, during the period beginning 1 year prior to the submission of an application under this paragraph and ending 1 year after the date on which the grant or contract is received; and

“(C) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

1 “(3) CRITERIA FOR AWARDING GRANTS OR
2 CONTRACTS.—In evaluating grant or contract appli-
3 cations received under this subsection, the Secretary
4 shall take into consideration—

5 “(A) the capacity of the entities to perform
6 the activities described in paragraph (4);

7 “(B) the service areas of the entity’s pro-
8 grams, in order to minimize overlap;

9 “(C) the plans of the entities involved to
10 provide incentives for physicians and other pre-
11 scribers to participate in the education pro-
12 gram, such as the availability of continuing
13 medical education credits; and

14 “(D) the methods proposed to provide the
15 educational materials through outreach and
16 interaction with prescribers in a setting, and
17 with a communications plan, designed to en-
18 hance the likelihood that prescribers will par-
19 ticipate, and will use the information to improve
20 the relative safety, relative effectiveness, and
21 relative cost of medication utilization.

22 “(4) USE OF FUNDS.—An entity shall use
23 amounts received under a grant or contract under
24 this subsection to carry out the following activities:

1 “(A) To hire and provide training to
2 nurses, pharmacists, or other individuals with
3 an appropriate clinical background to enable
4 such individuals to provide information and
5 educational outreach concerning the relative
6 safety, relative effectiveness, and relative cost of
7 prescription drugs and their alternatives as de-
8 scribed in subsection (a)(2) to healthcare pro-
9 viders who prescribe drugs in a manner that
10 prescribers find useful, convenient, and time ef-
11 ficient.

12 “(B) To identify healthcare providers who
13 will receive office visits from individuals who re-
14 ceive training under this subsection. Preference
15 for such office visits shall be given to healthcare
16 providers with a large number of total patients
17 or large number of patients receiving care
18 through Federal health programs including the
19 Medicare and Medicaid programs under titles
20 XVIII and XIX of the Social Security Act.

21 “(C) To conduct office visits to healthcare
22 providers who prescribe drugs.

23 “(D) To conduct other educational out-
24 reach activities with respect to healthcare pro-

1 viders who prescribe drugs, as approved by the
2 Secretary.

3 “(E) To conduct an evaluation of the effec-
4 tiveness of the program involved in changing
5 prescribing behavior and improving the quality
6 of medication use.

7 “(d) REGULATIONS.—The Secretary shall promul-
8 gate such regulations as may be required to carry out this
9 section, including regulations to prevent conflicts of inter-
10 est, to ensure the accuracy and timeliness of the informa-
11 tion in the educational materials, and to promote the effec-
12 tiveness of the prescriber education and outreach program.

13 “(e) EVALUATION.—The Secretary shall conduct an
14 evaluation of the effectiveness of the educational materials
15 and the prescriber education and outreach program under
16 this section.

17 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
18 is authorized to be appropriated, such sums as may be
19 necessary to carry out this section.”.

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