

110TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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 \_\_\_\_\_

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**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 Act of 2008” or the “IDEA Act”.

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 comparing  
8 the evidence available on the relative safety, relative  
9 effectiveness, and relative cost of prescription drugs  
10 for the same use distribution to healthcare providers  
11 who prescribe such drugs and their patients; and

12 “(2) under subsection (c) for the development  
13 and implementation of a program to appropriately  
14 train and deploy health professionals to educate phy-  
15 sicians and other drug prescribers concerning the  
16 relative safety, relative effectiveness, and relative  
17 cost of prescription drugs.

18 “(b) EDUCATIONAL MATERIAL GRANTS OR CON-  
19 TRACTS.—

20 “(1) IN GENERAL.—The Secretary, acting  
21 through the Director, shall award grants or con-  
22 tracts to eligible entities for the development and  
23 production of educational materials concerning the  
24 relative safety, relative effectiveness, and relative  
25 cost of prescription drugs, including generic and  
26 over-the-counter alternatives for the same use for

1 presentation to healthcare providers who prescribe  
2 such drugs and their patients. Such materials shall  
3 be based upon evidence-based information developed  
4 from peer-reviewed sources.

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

8 “(A) be a non-profit or governmental enti-  
9 ty that is able to demonstrate clinical expertise,  
10 including—

11 “(i) a medical school;

12 “(ii) an academic medical center;

13 “(iii) a school of pharmacy;

14 “(iv) a medical society;

15 “(v) a research institute; and

16 “(vi) any other entity determined ap-  
17 propriate by the Secretary;

18 “(B) receive no support from any entity  
19 that manufactures products used to treat the  
20 medical conditions discussed, or from any orga-  
21 nization funded by such entities, during the pe-  
22 riod beginning 1 year prior to the submission of  
23 an application under this paragraph and ending  
24 1 year after the date on which the grant or con-  
25 tract is received; and

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

5                   “(i) information on the **【therapeutic**  
6                   **category or categories】** for which the enti-  
7                   ty will develop and produce educational  
8                   materials using grant or contract funds;  
9                   and

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

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

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

20                   “(B) the **【therapeutic category or cat-**  
21                   **egories】** that the educational materials involved  
22                   will relate to, with a preference for minimizing  
23                   redundancy; and

24                   “(C) the quality of the proposed edu-  
25                   cational materials involved, including the ade-

1           quacy of the methods to be used to analyze the  
2           studies proposed to be relied upon, and the like-  
3           lihood that the materials will accurately present  
4           the available evidence.

5           “(4) USE OF FUNDS.—An entity shall use  
6           amounts received under a grant or contract under  
7           this subsection to—

8                   “(A) develop educational materials of the  
9                   type described in paragraph (1), including  
10                  monographs, brochures, readily available ref-  
11                  erence cards, handouts for patients, and other  
12                  materials in either written or electronic formats  
13                  (including electronic formats compatible with e-  
14                  prescribing) determined appropriate by the Sec-  
15                  retary;

16                   “(B) conduct tests concerning the effec-  
17                  tiveness of such educational materials with  
18                  healthcare providers and their patients; and

19                   “(C) prepare and submit to the Director  
20                  the educational materials [by therapeutic cat-  
21                  egory or class], and a report that provides evi-  
22                  dence supporting the accuracy of the informa-  
23                  tion and findings in the educational materials,  
24                  including studies relied upon to prepare such  
25                  materials, a description of the methods used to

1 analyze those studies, and any studies with con-  
2 flicting findings that were not included in the  
3 educational materials.

4 “(5) REVIEW OF EDUCATIONAL MATERIALS.—

5 “(A) IN GENERAL.—The Director shall re-  
6 view and approve proposed educational mate-  
7 rials submitted under paragraph (4)(C) within  
8 90 days of the receipt of such materials.

9 “(B) CLEARANCE OF EDUCATIONAL MATE-  
10 RIALS.—With respect to educational materials  
11 that have been reviewed and approved by the  
12 Director, the Secretary shall permit the grantee  
13 or contractor involved to include on such edu-  
14 cational materials the following statement:  
15 ‘These materials were compiled under a grant  
16 issued by the Department of Health and  
17 Human Services.’.

18 “(C) UPDATE OF MATERIALS.—Not later  
19 than 2 years after the date on which the edu-  
20 cational materials were approved by the Direc-  
21 tor, and every 2 years thereafter, the grantee or  
22 contractor involved shall submit updated mate-  
23 rials to the Director, including the studies used  
24 to develop such updates.

1           “(6) AVAILABILITY.—The Director shall ensure  
2           that educational materials developed under a grant  
3           or contract under this subsection shall be made pub-  
4           lically available and accessible, including through the  
5           Internet website of the Agency.

6           “(c) PRESCRIBER EDUCATION AND OUTREACH PRO-  
7           GRAM.—

8           “(1) IN GENERAL.—The Secretary, acting  
9           through the Director, shall award 10 grants or con-  
10          tracts to eligible entities for the development and im-  
11          plementation of programs to appropriately train and  
12          deploy healthcare professionals to educate physicians  
13          and other drug prescribers concerning the relative  
14          safety, relative effectiveness, and relative cost of pre-  
15          scription drugs, including generic and over-the-  
16          counter alternatives for the same use and to dis-  
17          tribute the educational materials developed under  
18          subsection (b) to physicians and other drug pre-  
19          scribers.

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

23                  “(A) be—

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

1 “(ii) a non-profit private entity;

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

4 “(iv) an academic institution;

5 “(B) receive no support from any entity  
6 that manufactures products used to treat the  
7 medical conditions discussed, or from any orga-  
8 nization funded by such entities, during the pe-  
9 riod beginning 1 year prior to the submission of  
10 an application under this paragraph and ending  
11 1 year after the date on which the grant or con-  
12 tract is received; and

13 “(C) submit to the Secretary an applica-  
14 tion at such time, in such manner, and con-  
15 taining such information as the Secretary may  
16 require.

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

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

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

1           “(C) the plans of the entities involved to  
2 provide incentives for physicians and other pre-  
3 scribers to participate in the education pro-  
4 gram, such as the availability of continuing  
5 medical education credits; and

6           “(D) the methods proposed to provide the  
7 educational materials through outreach and  
8 interaction with prescribers in a setting, and  
9 with a communications plan, designed to en-  
10 hance the likelihood that prescribers will par-  
11 ticipate, and will use the information to improve  
12 the relative safety, relative effectiveness, and  
13 relative cost of medication utilization.

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

17           “(A) To hire and provide training to  
18 nurses, pharmacists, or other individuals with  
19 an appropriate clinical background to enable  
20 such individuals to provide information and  
21 educational outreach concerning the relative  
22 safety, relative effectiveness, and relative cost of  
23 prescription drugs to healthcare providers who  
24 prescribe drugs in a manner that prescribers  
25 find useful, convenient, and time efficient.

1           “(B) To identify healthcare providers who  
2 will receive office visits from individuals who re-  
3 ceive training under this subsection. Preference  
4 for such office visits shall be given to healthcare  
5 providers with a large number of total patients  
6 or large number of patients receiving care  
7 through the Medicare program under title  
8 XVIII of the Social Security Act.

9           “(C) To conduct office visits to healthcare  
10 providers who prescribe drugs.

11           “(D) To conduct other educational out-  
12 reach activities with respect to healthcare pro-  
13 viders who prescribe drugs, as approved by the  
14 Secretary.

15           “(E) To conduct an evaluation of the effec-  
16 tiveness of the program involved in changing  
17 prescribing behavior and improving the quality  
18 of medication use.

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

1           “(e) EVALUATION.—The Secretary shall conduct an  
2 evaluation of the effectiveness of the educational materials  
3 and the prescriber education and outreach program under  
4 this section.

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