II

111TH CONGRESS
1ST SESSION

# S. 767

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

APRIL 1, 2009

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

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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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Independent Drug Education and Outreach Act of 2009''.

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

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

**"SEC. 904. PRESCRIPTION DRUG EDUCATION AND OUTREACH.**

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

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

"(2) under subsection (c) for the development and implementation of a program to appropriately train and deploy health professionals to educate physicians and other drug prescribers concerning the relative safety, relative effectiveness, and relative cost of prescription drugs, non-prescription drugs, and non-drug interventions for treating selected conditions.

"(b) EDUCATIONAL MATERIAL GRANTS OR CONTRACTS.—

"(1) IN GENERAL.—The Secretary, acting through the Director, shall award grants or contracts to eligible entities for the development and

production of educational materials concerning the evidence available on the relative safety, relative effectiveness, and relative cost of prescription drugs, non-prescription drugs, and non-drug interventions for treating selected conditions, for presentation to healthcare providers who prescribe such drugs and their patients.

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

''(A) be a non-profit or governmental entity that is able to demonstrate clinical expertise, including—

''(i) a medical school;

''(ii) an academic medical center;

''(iii) a school of pharmacy;

''(iv) a medical society;

''(v) a pharmacist society;

''(vi) a research institute; and

''(vii) any other entity determined appropriate by the Secretary;

''(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 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 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, including—

''(i) information on the conditions for which the entity will develop and produce educational materials using grant or contract funds; and

''(ii) a plan for ensuring the effectiveness 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 applications 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 preference for minimizing redundancy; and

''(C) the quality of the proposed educational materials involved, including—

''(i) whether materials are based upon peer-reviewed sources or based upon scientific research which conforms to the accepted standards of experimental design, data collection, analysis, and interpretation;

''(ii) the likelihood that the materials will accurately reflect the comprehensive body of available evidence that is accepted within the practice of medicine; and

''(iii) the adequacy of the methods to be used to analyze the studies proposed to be relied upon.

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

''(A) develop educational materials of the type described in paragraph (1), including monographs, brochures, readily available reference cards, handouts for patients, and other materials in either written or electronic formats (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:

'These materials were compiled under a grant issued by the Department of Health and Human Services.'.

''(C) UPDATE OF MATERIALS.—As needed, but not later than 2 years after the date on which the educational materials were approved by the Director, the grantee or contractor involved shall submit updated materials to the Director, including the studies used to develop such updates.

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

''(c) PRESCRIBER EDUCATION AND OUTREACH PROGRAM.—

''(1) IN GENERAL.—The Secretary, acting through the Director, shall award 10 grants or contracts to eligible entities for the development and implementation of programs to appropriately train and deploy healthcare professionals to educate physicians and other drug prescribers concerning the relative safety, relative effectiveness, and relative cost of prescription 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.

''(3) CRITERIA FOR AWARDING GRANTS OR CONTRACTS.—In evaluating grant or contract applications 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 service areas of the entity's programs, in order to minimize overlap;

''(C) the plans of the entities involved to provide incentives for physicians and other prescribers to participate in the education program, such as the availability of continuing medical education credits; and

''(D) the methods proposed to provide the educational materials through outreach and interaction with prescribers in a setting, and with a communications plan, designed to enhance the likelihood that prescribers will participate, and will use the information to improve the relative safety, relative effectiveness, and relative cost of medication utilization.

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

"(A) To hire and provide training to nurses, pharmacists, or other individuals with an appropriate clinical background to enable such individuals to provide information and educational outreach concerning the relative safety, relative effectiveness, and relative cost of prescription drugs and their alternatives as described in subsection (a)(2) to healthcare providers who prescribe drugs in a manner that prescribers find useful, convenient, and time efficient.

"(B) To identify healthcare providers who will receive office visits from individuals who receive training under this subsection. Preference for such office visits shall be given to healthcare providers with a large number of total patients or large number of patients receiving care through Federal health programs including the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act.

"(C) To conduct office visits to healthcare providers who prescribe drugs.

"(D) To conduct other educational outreach activities with respect to healthcare pro-

viders who prescribe drugs, as approved by the Secretary.

''(E) To conduct an evaluation of the effectiveness of the program involved in changing prescribing behavior and improving the quality of medication use.

''(d) REGULATIONS.—The Secretary shall promulgate such regulations as may be required to carry out this section, including regulations to prevent conflicts of interest, to ensure the accuracy and timeliness of the information in the educational materials, and to promote the effectiveness of the prescriber education and outreach program.

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

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

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