

“(1) LESS THAN \$10,000,000.—If the amount of appropriations for this part in a fiscal year is less than \$10,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3)(A).

“(2) LESS THAN \$20,000,000.—If the amount of appropriations in a fiscal year is less than \$20,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under subparagraphs (A) and (B) of section 1241(b)(3).

“(3) LESS THAN \$30,000,000.—If the amount of appropriations for this part in a fiscal year is less than \$30,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3).

“(4) \$30,000,000 OR MORE.—If the amount of appropriations for this part in a fiscal year is \$30,000,000 or more, the Secretary shall divide such funding evenly among all States.

“SEC. 1282. AUTHORIZATION OF APPROPRIATIONS.

“For the purpose of carrying out this part, there is authorized to be appropriated \$100,000,000 for each of fiscal years 2010 through 2015.”.

SEC. 3506. PROGRAM TO FACILITATE SHARED DECISIONMAKING.

Part D of title IX of the Public Health Service Act, as amended by section 3503, is further amended by adding at the end the following:

“SEC. 936. PROGRAM TO FACILITATE SHARED DECISIONMAKING.

“(a) PURPOSE.—The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decisionmaking, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

“(b) DEFINITIONS.—In this section:

“(1) PATIENT DECISION AID.—The term ‘patient decision aid’ means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

“(2) PREFERENCE SENSITIVE CARE.—The term ‘preference sensitive care’ means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

“(c) ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS FOR PREFERENCE SENSITIVE CARE.—

“(1) CONTRACT WITH ENTITY TO ESTABLISH STANDARDS AND CERTIFY PATIENT DECISION AIDS.—

“(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the entity with a contract under section 1890 of the Social Security Act. Such contract shall provide that the entity perform the duties described in paragraph (2).

“(B) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contract under subparagraph (A).

“(C) PERIOD OF CONTRACT.—A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

“(2) DUTIES.—The following duties are described in this paragraph:

“(A) DEVELOP AND IDENTIFY STANDARDS FOR PATIENT DECISION AIDS.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

“(B) ENDORSE PATIENT DECISION AIDS.—The entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference sensitive care.

“(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS.—

“(1) IN GENERAL.—The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish a program to award grants or contracts—

“(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

“(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make informed decisions about patient care and can be easily incorporated into a broad array of practice settings; and

“(C) to educate providers on the use of such materials, including through academic curricula.

“(2) REQUIREMENTS FOR PATIENT DECISION AIDS.—Patient decision aids developed and produced pursuant to a grant or contract under paragraph (1)—

“(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decisionmaking with health care providers;

“(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

“(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

“(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

“(3) DISTRIBUTION.—The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

“(4) NONDUPLICATION OF EFFORTS.—The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

“(e) GRANTS TO SUPPORT SHARED DECISIONMAKING IMPLEMENTATION.—

“(1) IN GENERAL.—The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

“(2) SHARED DECISIONMAKING RESOURCE CENTERS.—

“(A) IN GENERAL.—The Secretary shall provide grants for the establishment and support of Shared Decisionmaking Resource Centers (referred to in this subsection as ‘Centers’) to provide technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers.

“(B) OBJECTIVES.—The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decisionmaking through—

“(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

“(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

“(3) SHARED DECISIONMAKING PARTICIPATION GRANTS.—

“(A) IN GENERAL.—The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques and to assess the use of such techniques.

“(B) PREFERENCE.—In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care

providers who participate in training by Shared Decision-making Resource Centers or comparable training.

“(C) LIMITATION.—Funds under this paragraph shall not be used to purchase or implement use of patient decision aids other than those certified under the process identified in subsection (c).

“(4) GUIDANCE.—The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

“(f) FUNDING.—For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.”.

SEC. 3507. PRESENTATION OF PRESCRIPTION DRUG BENEFIT AND RISK INFORMATION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

(b) REVIEW AND CONSULTATION.—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women’s and pediatric health.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides—

- (1) the determination by the Secretary under subsection (a); and
- (2) the reasoning and analysis underlying that determination.

(d) AUTHORITY.—If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

(e) CLARIFICATION.—Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.

SEC. 3508. DEMONSTRATION PROGRAM TO INTEGRATE QUALITY IMPROVEMENT AND PATIENT SAFETY TRAINING INTO CLINICAL EDUCATION OF HEALTH PROFESSIONALS.

(a) IN GENERAL.—The Secretary may award grants to eligible entities or consortia under this section to carry out demonstration projects to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical