

**§ 299b-36. Program to facilitate shared decision-making**

**(a) Purpose**

The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages<sup>1</sup> the patient, caregiver or authorized representative in decisionmaking, provides<sup>2</sup> patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates<sup>3</sup> 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<sup>4</sup> 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 1395aaa of this title. Such contract shall provide that the entity perform the duties described in paragraph (2).

**(B) Timing for first contract**

As soon as practicable after March 23, 2010, 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 con-

tract 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<sup>5</sup> 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 produce 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 edu-

<sup>1</sup> So in original. Probably should be “engage”.

<sup>2</sup> So in original. Probably should be “provide”.

<sup>3</sup> So in original. Probably should be “facilitate”.

<sup>4</sup> So in original. Probably should be “option. The”.

<sup>5</sup> So in original.

national 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 partici-

pate in training by Shared Decisionmaking 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.

(July 1, 1944, ch. 373, title IX, §936, as added Pub. L. 111-148, title III, §3506, Mar. 23, 2010, 124 Stat. 527.)

PRIOR PROVISIONS

A prior section 936 of act July 1, 1944, was renumbered section 946 and is classified to section 299c-5 of this title.

**§ 299b-37. Dissemination and building capacity for research**

**(a) In general**

**(1) Dissemination**

The Office of Communication and Knowledge Transfer (referred to in this section as the “Office”) at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1320e(b) of this title (referred to in this section as the “Institute”) and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for-profit, and academic sources.

**(2) Requirements**

The Office shall provide for the dissemination of the Institute’s research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the re-