whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

(f) Reporting to the Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1395aaa of this title, as determined by the Secretary.

(g) Evaluation and report

The Secretary shall submit to the relevant committees of Congress a report which shall—

(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

(2) assess changes in overall health care resource use by targeted individuals;

(3) assess patient and prescriber satisfaction with MTM services;

(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

(h) Grants or contracts to fund development of performance measures

The Secretary may, through the quality measure development program under section 299b–31 of this title, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

(July 1, 1944, ch. 373, title IX, § 935, as added and amended Pub. L. 111–148, title III, § 3503, title X, § 10501(f)(4), Mar. 23, 2010, 124 Stat. 516, 996.)

Editorial Notes

PRIOR PROVISIONS

A prior section 935 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

AMENDMENTS

2010—Subsec. (b)(3). Pub. L. 111–148, § 10501(f)(4), made technical amendment to reference in original act which appears in text as reference to section 280g–12 of this title.

§ 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[1] the patient, caregiver or authorized representative in decisionmaking, provides[2] patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates[3] 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[4] 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-

[1] So in original. Probably should be ''engage''.
[2] So in original. Probably should be ''provide''.
[3] So in original. Probably should be ''facilitate''.
[4] So in original. Probably should be ''option. The''.

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[5] 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 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 partici-

[5] So in original.

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.)

Editorial Notes

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 research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

(b) Incorporation of research findings

The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

(c) Feedback

The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

(d) Rule of construction

Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1320e(d)(8) of this title.

(e) Training of researchers

The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1320e(d)(9) of this title.

(f) Building data for research

The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

(g) Authority to contract with the Institute

Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.

(July 1, 1944, ch. 373, title IX, § 937, as added Pub. L. 111–148, title VI, § 6301(b), Mar. 23, 2010, 124 Stat. 738.)