entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for a sustainable business model that may include a system of—

(i) charging fees to institutions and providers that receive technical support from the entity; and

(ii) reducing or eliminating such fees for such institutions and providers that serve low-income populations; and

(B) such other information as the Director may require.

(2) Implementation award

To receive a grant or contract under subsection (a)(2), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for implementation of a model or practice identified in the research conducted by the Center including—

(i) financial cost, staffing requirements, and timeline[2] for implementation; and

(ii) pre- and projected post-implementation quality measure performance data in targeted improvement areas identified by the Secretary; and

(B) such other information as the Director may require.

(d) Matching funds

The Director may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Evaluation

(1) In general

The Director shall evaluate the performance of each entity that receives a grant or contract under this section. The evaluation of an entity shall include a study of—

(A) the success of such entity in achieving the implementation, by the health care institutions and providers assisted by such entity, of the models and practices identified in the research conducted by the Center under section 299b–33 of this title;

(B) the perception of the health care institutions and providers assisted by such entity regarding the value of the entity; and

(C) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity.

(2) Effect of evaluation

Based on the outcome of the evaluation of the entity under paragraph (1), the Director shall determine whether to renew a grant or contract with such entity under this section.

[2] So in original. Probably should be ''a timeline''.

(f) Coordination

The entities that receive a grant or contract under this section shall coordinate with health information technology regional extension centers under section 300jj–32(c) of this title and the primary care extension program established under section 280g–12 of this title regarding the dissemination of quality improvement, system delivery reform, and best practices information.

(July 1, 1944, ch. 373, title IX, § 934, as added and amended Pub. L. 111–148, title III, § 3501, title X, § 10501(f)(3), Mar. 23, 2010, 124 Stat. 511, 996.)

PRIOR PROVISIONS

A prior section 934 of act July 1, 1944, was renumbered section 944 and is classified to section 299c–3 of this title.

AMENDMENTS

2010—Subsecs. (b)(1)(A), (f). Pub. L. 111–148, § 10501(f)(3), made technical amendment to reference in original act which appears in text as reference to section 280g–12 of this title.

§ 299b–35. Grants or contracts to implement medication management services in treatment of chronic diseases

(a) In general

The Secretary, acting through the Patient Safety Research Center established in section 299b–33 of this title (referred to in this section as the ''Center''), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as ''MTM'') services provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

(b) Eligible entities

To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

(2) submit to the Secretary a plan for achieving long-term financial sustainability;

(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 256a–1 of this title or in collaboration with primary care extension programs established in section 280g–12 of this title;

(4) submit a plan for meeting the requirements under subsection (c); and

(5) submit to the Secretary such other information as the Secretary may require.

(c) MTM services to targeted individuals

The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

(d) Targeted individuals

MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

(2) take any ''high risk'' medications;

(3) have 2 or more chronic diseases, as identified by the Secretary; or

(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

(e) Consultation with experts

In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine 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.)

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 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[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 edu-

[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''.
[5] So in original.