I

111TH CONGRESS
1ST SESSION

H. R. 2580

To amend title XVIII of the Social Security Act to provide for the establishment of shared decision making standards and requirements and to establish a pilot program for the implementation of shared decision making under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2009

Mr. BLUMENAUER introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide for the establishment of shared decision making standards and requirements and to establish a pilot program for the implementation of shared decision making under the Medicare Program.

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 ''Empowering Medicare Patient Choices Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) The Dartmouth Atlas Project's work documenting regional variations in medical care has found both underuse, or the failure to deliver needed evidence-based care, and overuse, or the delivery of unnecessary supply-sensitive care.

(2) The Dartmouth Atlas Project has also found that many clinical decisions physicians make for elective medical treatments are driven by local medical opinion, rather than sound science or the preferences of well-informed patients. For example, the Dartmouth Atlas Project found that, among the 306 Hospital Referral Regions in the United States during the period of 2002 through 2003, the incidence of surgery for back pain-related conditions and joint replacement for chronic arthritis of the hip and knee varied 5.9-, 5.6-, and 4.8-fold, respectively, from the lowest to the highest region.

(3) Discretionary surgery for the following common conditions accounts for 40 percent of Medicare spending for inpatient surgery: early stage cancer of the prostate; early stage cancer of the breast; osteoarthritis of the knee; osteoarthritis of the hip; osteoarthritis of the spine; chest pain due to coronary artery disease; stroke threat from carotid artery dis-

ease, ischemia due to peripheral artery disease; gall stones; and enlarged prostate.

(4) Decisions that involve values trade-offs between the benefits and harms of 2 or more clinically appropriate alternatives should depend on the individual patient's informed choice. In everyday practice, however, patients typically delegate decision making to their physicians who may not have good information on the patient's true preferences.

(5) The current standard of medical care in the United States fails to adequately ensure that patients are informed about their treatment options and the risks and benefits of those options. This leads to patients getting medical treatments they may not have wanted had they been fully informed of their treatment options and integrated into the decision making process.

(6) Patient decision aids are tools designed to help people participate in decision making about health care options. Patient decision aids provide information on treatment options and help patients clarify and communicate the personal value they associate with different features of treatment options. Patient decision aids do not advise people to choose one treatment option over another, nor are they

meant to replace practitioner consultation. Instead, they prepare patients to make informed, value-based decisions with their physician.

(7) The Lewin Group estimated that the change in spending resulting from the use of patient decision aids for each of 11 conditions using per-procedure costs estimated for the Medicare population studied, assuming full implementation of such patient decision aids in 2010, would save as much as $4,000,000,000.

SEC. 3. DEFINITIONS.

In this Act:

(1) ELIGIBLE PROVIDER.—

(A) IN GENERAL.—The term ''eligible provider'' means the following:

(i) A primary care practice.

(ii) A specialty practice.

(iii) A multispecialty group practice.

(iv) A hospital.

(v) A rural health clinic.

(vi) A Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act (42 U.S.C. 1395x(aa)(4)).

(vii) An integrated delivery system.

(viii) A State cooperative.

(B) INCLUSION OF MEDICARE ADVANTAGE PLANS.—Such term includes a Medicare Advantage plan offered by a Medicare Advantage organization under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.).

(2) PATIENT DECISION AID.—The term ''patient decision aid'' means an educational tool (such as the Internet, a video, or a pamphlet) that helps patients (or, if appropriate, the family caregiver of the patient) 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.

(3) 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 regarding the benefits, harms, and scientific evidence for each treatment option. The use of such care should de-

pend on informed patient choice among clinically appropriate treatment options. Such term includes medical care for the conditions identified in section 5(g).

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(5) SHARED DECISION MAKING.—The term ''shared decision making'' means a collaborative process between patient and clinician that engages the patient in decision making, provides patients with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

(6) STATE COOPERATIVE.—The term ''State cooperative'' means an entity that includes the State government and at least one other health care provider which is set up for the purpose of testing shared decision making and patient decision aids.

SEC. 4. ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS.

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

(1) CONTRACT.—

(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient

decision aids and a certification process for patient decision aids for use in the Medicare program and by other interested parties, the Secretary shall identify and have in effect a contract with an entity that meets the requirements described in paragraph (4). 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 Act, 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).

(D) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under subparagraph (A).

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

(A) OPERATE AN OPEN AND TRANSPARENT PROCESS.—The entity shall conduct its business

in an open and transparent manner and provide the opportunity for public comment on the activities described in subparagraphs (B) and (C).

(B) ESTABLISH STANDARDS FOR PATIENT DECISION AIDS.—

(i) IN GENERAL.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to establish consensus-based standards, such as those developed by the International Patient Decision Aid Standard Collaboration, to determine which patient decision aids are high quality patient decision aids.

(ii) DRAFT OF PROPOSED STANDARDS.—The entity shall make a draft of proposed standards available to the public.

(iii) 60-DAY COMMENT PERIOD.—Beginning on the date the entity makes a draft of the proposed standards available under clause (ii), the entity shall provide a 60-day period for public comment on such draft.

(iv) FINAL STANDARDS.—

(I) IN GENERAL.—The standards established by the entity under this

subparagraph shall be adopted by the board of the entity.

(II) PUBLIC AVAILABILITY.—The entity shall make such standards available to the public.

(C) CERTIFY PATIENT DECISION AIDS.—The entity shall review patient decision aids and certify whether patient decision aids meet the standards established under subparagraph (B) and offer a balanced presentation of treatment options from both the clinical and patient experience perspectives. In conducting such review and certification, the entity shall give priority to the review and certification of patient decision aids for conditions identified in section 5(g).

(3) REPORT TO THE EXPERT PANEL.—The entity shall submit to the expert panel established under subsection (b) a report on the standards established for patient decision aids under paragraph (2)(B) and patient decision aids that are certified as meeting such standards under paragraph (2)(C).

(4) REQUIREMENTS DESCRIBED.—The following requirements are described in this paragraph:

(A) PRIVATE NONPROFIT.—The entity is a private nonprofit organization governed by a board.

(B) EXPERIENCE.—The entity shall be able to demonstrate experience with—

(i) consumer engagement;

(ii) standard setting;

(iii) health literacy;

(iv) health care quality and safety issues;

(v) certification processes;

(vi) measure development; and

(vii) evaluating health care quality.

(C) MEMBERSHIP FEES.—If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

(b) EXPERT PANEL.—

(1) ESTABLISHMENT.—Not later than 120 days after the date of enactment of this Act, the Sec-

retary shall establish an expert panel to make recommendations to the Secretary regarding which patient decision aids should be implemented, appropriate training for health care providers on patient decision aids and shared decision making, and appropriate quality measures for use in the pilot program under section 5 and under section 1899 of the Social Security Act, as added by section 6.

(2) DUTIES.—The expert panel shall carry out the following duties:

(A) Approve patient decision aids, from among those patient decision aids certified under paragraph (2)(C) of subsection (a) by the entity with a contract under such subsection, for use in the pilot program under section 5 (including to the extent practicable, patient decision aids for the medical care of the conditions described in section 5(g) and under section 1899 of the Social Security Act, as added by section 6.

(B) Review current training curricula for health care providers on patient decision aids and shared decision making and recommend a training process for eligible providers participating in the pilot program under section 5 on

the use of such approved patient decision aids and shared decision making.

(C) Review existing quality measures regarding patient knowledge, value concordance, and health outcomes that have been endorsed through a consensus-based process and recommend appropriate quality measures for selection under section 5(h)(1).

(3) APPOINTMENT.—The expert panel shall be composed of 13 members appointed by the Secretary from among leading experts in shared decision making of whom—

(A) 2 shall be researchers;

(B) 2 shall be primary care physicians;

(C) 2 shall be from surgical specialties;

(D) 2 shall be patient or consumer community advocates;

(E) 2 shall be nonphysician health care providers (such as nurses, nurse practitioners, and physician assistants);

(F) 1 shall be from an integrated multispecialty group practice;

(G) 1 shall be from the National Cancer Institute; and

(H) 1 shall be from the Centers for Disease Control and Prevention.

(4) REPORT.—Not later than 2 years after such date of enactment and each year thereafter until the date of the termination of the expert panel under paragraph (5), the expert panel shall submit to the Secretary a report on the patient decision aids approved under paragraph (2)(A), the training process recommended under paragraph (2)(B), the quality measures recommended under paragraph (2)(C), and recommendations on other conditions or medical care the Secretary may want to include in the pilot program under section 5.

(5) TERMINATION.—The expert panel shall terminate on such date as the Secretary determines appropriate.

(c) QUALITY MEASURE DEVELOPMENT.—

(1) IN GENERAL.—Section 1890(b)(1)(A) of the Social Security Act (42 U.S.C. 1395aaa(b)(1)(A)) is amended—

(A) in clause (ii), by striking ''and'' at the end; and

(B) by adding at the end the following new clause:

''(iv) that address conditions described in section 5(g) of the Empowering Medicare Patient Choices Act and regional practice variations under this title; and''.

(2) CONFORMING AMENDMENT.—Section 1890(d) of the Social Security Act (42 U.S.C. 1395aaa(d)) is amended—

(A) by inserting ''(other than subsection (b)(1)(A)(iv))'' after ''this section''; and

(B) by adding at the end the following new sentence: ''For provisions relating to funding for the duties described in subsection (b)(1)(A)(iv), see section 5(l) of the Empowering Medicare Patient Choices Act.''.

SEC. 5. ESTABLISHMENT OF SHARED DECISION MAKING PILOT PROGRAM UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Not later than 12 months after the date of enactment of this Act, the Secretary shall establish a pilot program to provide for the phased-in development, implementation, and evaluation of shared decision making under the Medicare program using patient decision aids to meet the objective of improving the understanding by Medicare beneficiaries of their medical treatment options, as compared to comparable Medicare bene-

ficiaries who do not participate in a shared decision making process using patient decision aids.

(b) INITIAL IMPLEMENTATION (PHASE I).—

(1) IN GENERAL.—During the initial implementation of the pilot program under this section (referred to in this section as ''Phase I'' of the pilot program), the Secretary shall enroll in the pilot program not more than 15 eligible providers who have experience in implementing, and have invested in the necessary infrastructure to implement, shared decision making using patient decision aids for a period of 3 years.

(2) APPLICATION.—An eligible provider seeking to participate in the pilot program during phase I shall submit to the Secretary an application at such time and containing such information as the Secretary may require.

(3) PREFERENCE.—In enrolling eligible providers in the pilot program during phase I, the Secretary shall give preference to eligible providers that—

(A) have documented experience in using patient decision aids for the conditions identified in subsection (g) and in using shared decision making;

(B) have the necessary information technology infrastructure to collect the information required by the Secretary for reporting purposes;

(C) are trained in how to use patient decision aids and shared decision making; and

(D) would be eligible to receive financial assistance as a Shared Decision Making Resource Center under subsection (c).

(c) SHARED DECISION MAKING RESOURCE CENTERS.—

(1) IN GENERAL.—The Secretary shall provide financial assistance for the establishment and support of Shared Decision Making Resource Centers (referred to in this section as ''centers'') to provide technical assistance to eligible 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 decision making by eligible providers under the Medicare program.

(2) AFFILIATION.—Centers shall be affiliated with a United States-based organization or group that applies for and is awarded financial assistance under this subsection. The Secretary shall provide fi-

nancial assistance to centers under this subsection on the basis of merit.

(3) OBJECTIVES.—The objective of a center is to enhance and promote the adoption of patient decision aids and shared decision making through—

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

(B) the dissemination of best practices and research on the implementation and effective use of patient decision aids; and

(C) providing assistance to eligible providers applying to participate or participating in phase II of the pilot program under this section or under section 1899 of the Social Security Act, as added by section 6.

(4) REGIONAL ASSISTANCE.—Each center shall aim to provide assistance and education to all eligible providers in a region, including direct assistance to the following eligible providers:

(A) Public or not-for-profit hospitals or critical access hospitals (as defined in section 1861(mm)(1) of the Social Security Act (42 U.S.C. 1395x(mm)(1)).

(B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act (42 U.S.C. 1395x(aa)(4)).

(C) Entities that are located in a rural area or in an area that serves uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

(5) FINANCIAL ASSISTANCE.—

(A) IN GENERAL.—The Secretary may provide financial assistance for a period of 8 years to any regional center established or supported under this subsection.

(B) COST-SHARING REQUIREMENT.—

(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall not provide as financial assistance under this subsection more than 50 percent of the capital and annual operating and maintenance funds required to establish and support such a center.

(ii) WAIVER OF COST-SHARING REQUIREMENT.—The Secretary may waive the limitation under clause (i) if the Secretary determines that, as a result of national economic conditions, such limitation would be detrimental to the pilot program under this section. If the Secretary waives such limitation under the preceding sentence, the Secretary shall submit to Congress a report containing the Secretary's justification for such waiver.

(6) NOTICE OF PROGRAM DESCRIPTION AND AVAILABILITY OF FUNDS.—The Secretary shall publish in the Federal Register, not later than 12 months after the date of the enactment of this Act, a draft description of a program for establishing and supporting regional centers under this subsection. Such draft description shall include the following:

(A) A detailed explanation of the program and the program goals.

(B) Procedures to be followed by applicants for financial assistance.

(C) Criteria for determining which applicants are qualified to receive financial assistance.

(D) Maximum support levels expected to be available to centers under the program.

(7) APPLICATION REVIEW.—The Secretary shall review each application for financial assistance under this subsection based on merit. In making a decision whether to approve such application and provide financial assistance, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

(A) the ability of the applicant to provide assistance to particular categories of eligible providers with respect to the implementation and effective use of, and training on, patient decision aids;

(B) the geographical diversity and extent of the service area of the applicant; and

(C) the percentage of funding for the center that would be provided as financial assistance under this subsection and the amount of any funding or in-kind commitment from sources of funding in addition to the financial assistance provided under this subsection.

(8) BIENNIAL EVALUATION.—Each center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation

panel appointed by the Secretary. Each such evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and officials of the Federal Government. Each evaluation panel shall measure the performance of the center involved against the objectives specified in paragraph (3). The Secretary shall not continue to provide financial assistance to a center under this subsection unless the most recent evaluation under this paragraph with respect to the center is overall positive.

(d) EXPANDED IMPLEMENTATION (PHASE II).—

(1) IN GENERAL.—Subject to paragraph (2), during the 3-year period beginning after the completion of phase I of the pilot program (referred to in this section as ''phase II'' of the pilot program), the Secretary shall enroll additional eligible providers to implement shared decision making using patient decision aids under the pilot program under this section. The Secretary may allow eligible providers to enroll in the pilot program on a regular basis during phase II.

(2) CONTINGENCY.—The Secretary shall not implement phase II of the pilot program if the Secretary finds, not later than 90 days after the date

of submittal of the interim report under subsection (i)(2)(A), that the continued implementation of shared decision making is not in the best interest of Medicare beneficiaries.

(3) PREFERENCE.—In enrolling eligible providers in the pilot program during phase II, the Secretary shall include, to the extent practicable, eligible providers that—

(A) have or can acquire the infrastructure necessary to implement shared decision making supported by patient decision aids approved by the expert panel established under section 4(b) in a timely manner; or

(B) have training in the use of patient decision aids or will participate in training for health care professionals who will be involved in such use (as specified by the Secretary).

(e) GUIDANCE.—The Secretary may, in consultation with the expert panel established under section 4(b), issue guidance to eligible providers participating in the pilot program under this section on the use of patient decision aids approved by the expert panel.

(f) REQUIREMENTS.—

(1) IMPLEMENTATION OF APPROVED PATIENT DECISION AIDS.—

(A) IN GENERAL.—During phase II of the pilot program under this section, an eligible provider participating in the pilot program shall incorporate 1 or more patient decision aids approved by the expert panel established under section 4(b) in furnishing items and services to Medicare beneficiaries with respect to 1 or more of the conditions identified in subsection (g), together with ongoing support involved in furnishing such items and services.

(B) DEFINED CLINICAL PROCESS.—During each phase of the pilot program under this section, the eligible provider shall establish and implement a defined clinical process under which, in the case of a Medicare beneficiary with 1 or more of such conditions, the eligible provider offers the Medicare beneficiary shared decision making (supported by such a patient decision aid) and collects information on the quality of patient decision making with respect to the Medicare beneficiary.

(2) FOLLOW-UP COUNSELING VISIT.—

(A) IN GENERAL.—During each phase of the pilot program under this section, an eligible provider participating in the pilot program

under this section shall routinely schedule Medicare beneficiaries for a counseling visit after the viewing of such a patient decision aid to answer any questions the beneficiary may have with respect to the medical care of the condition involved and to assist the beneficiary in thinking through how their preferences and concerns relate to their medical care.

(B) PAYMENT FOR FOLLOW-UP COUNSELING VISIT.—The Secretary shall establish procedures for making payments for such counseling visits provided to Medicare beneficiaries during each phase of the pilot program under this section. Such procedures shall provide for the establishment—

(i) of a code (or codes) to represent such services; and

(ii) of a single payment amount for such service that includes the professional time of the health care provider and a portion of the reasonable costs of the infrastructure of the eligible provider.

(C) LIMITATION.—In the case of an eligible provider that is a Medicare Advantage plan,

such eligible provider may not receive payment for such services.

(3) WAIVER OF COINSURANCE.—The Secretary shall establish procedures under which an eligible provider participating in the pilot program under this section may, in the case of a low-income Medicare beneficiary (as determined by the Secretary), waive any coinsurance or copayment that would otherwise apply for the follow-up counseling visit provided to such Medicare beneficiary under paragraph (2).

(4) COSTS OF IMPLEMENTATION.—

(A) IN GENERAL.—Subject to subparagraph (B), during each phase of the pilot program, an eligible provider participating in the pilot program shall be responsible for the costs of selecting, purchasing, and incorporating such patient decision aids into the group practice, reporting data on quality measures selected under subsection (h)(1), and recording outcomes under the pilot program.

(B) FINANCIAL SUPPORT.—During each such phase, the Secretary may, in addition to payments for counseling visits under paragraph (2), provide financial support to an eligible pro-

vider participating in the pilot program to acquire the infrastructure necessary to participate in the pilot program, including the development of clinical pathways to assure that Medicare beneficiaries have access to high-quality shared decision making, the reporting of data on quality measures selected under subsection (h)(1), and the recording of outcomes under the pilot program after phase I of the pilot program (as determined appropriate by the Secretary).

(g) PREFERENCE SENSITIVE CARE DESCRIBED.—The patient decision aids approved under section 4(b)(2)(A) shall, to the extent practicable, include patient decision aids for medical care of the following conditions:

(1) Arthritis of the hip and knee.

(2) Chronic back pain.

(3) Chest pain (stable angina).

(4) Enlarged prostate (benign prostatic hypertrophy, or BPH).

(5) Early-stage prostate cancer.

(6) Early-stage breast cancer.

(7) End-of-life care.

(8) Peripheral vascular disease.

(9) Gall stones.

(10) Threat of stroke from carotid artery disease.

(11) Any other condition the Secretary identifies as appropriate.

(h) QUALITY MEASURES.—

(1) SELECTION.—

(A) IN GENERAL.—During each phase of the pilot program, the Secretary shall measure the quality and implementation of shared decision making. For purposes of making such measurements, the Secretary shall select, from among those quality measures recommended by the expert panel under section 4(b)(2)(C), consensus-based quality measures that assess Medicare beneficiaries' knowledge of the options for medical treatment relevant to their medical condition, as well as the benefits and drawbacks of those medical treatment options, and the Medicare beneficiaries' goals and concerns regarding their medical care.

(B) RISK ADJUSTMENT.—In order to ensure accurate measurement across quality measures and eligible providers, the Secretary may risk adjust the quality measures selected under this paragraph to control for external

factors, such as cognitive impairment, dementia, and literacy.

(2) REPORTING DATA ON MEASURES.—During each such phase, an eligible provider participating in the pilot program shall report to the Secretary data on quality measures selected under paragraph (1) in accordance with procedures established by the Secretary.

(3) FEEDBACK ON MEASURES.—During each such phase, the Secretary shall provide confidential reports to eligible providers participating in the pilot program on the performance of the eligible provider on quality measures selected by the Secretary under paragraph (1), the aggregate performance of all eligible providers participating in the pilot program, and any improvements in such performance.

(i) EVALUATIONS AND REPORTS.—

(1) INDEPENDENT EVALUATION.—The Secretary shall enter into a contract with an entity that has knowledge of shared decision making programs and demonstrated experience in the evaluation of such programs for the conduct of an independent evaluation of each phase of the pilot program under this section.

(2) REPORTS BY ENTITY CONDUCTING INDEPENDENT EVALUATION.—

(A) INTERIM REPORT.—Not later than 2 years after the implementation of phase I of the pilot program, the entity with a contract under paragraph (1) shall submit to the Secretary a report on the initial results of the independent evaluation conducted under such paragraph.

(B) FINAL REPORT.—Not later then 4 years after the implementation of phase II of the pilot program, such entity shall submit to the Secretary a report on the final results of such independent evaluation.

(C) CONTENTS OF REPORT.—Each report submitted under this paragraph shall—

(i) include an assessment of—

(I) quality measures selected under subsection (h)(1);

(II) Medicare beneficiary and health care provider satisfaction under the applicable phase of the pilot program;

(III) utilization of medical services for Medicare beneficiaries with 1 or more of the conditions described in

subsection (g) and other Medicare beneficiaries as determined appropriate by the Secretary;

(IV) appropriate utilization of shared decision making by eligible providers under the applicable phase of the pilot program;

(V) savings to the Medicare program under title XVIII of the Social Security Act; and

(VI) the costs to eligible providers participating in the pilot program of selecting, purchasing, and incorporating approved patient decision aids and meeting reporting requirements under the applicable phase of the pilot program; and

(ii) identify the characteristics of individual eligible providers that are most effective in implementing shared decision making under the applicable phase of the pilot program.

(3) REPORT BY THE SECRETARY.—Not later than 12 months after the completion of phase II of the pilot program, the Secretary shall submit to

Congress a report on the pilot program that includes—

(A) the results of the independent evaluation conducted under paragraph (2);

(B) an evaluation of the impact of the pilot program under this section, including the impact—

(i) of the use of patient decision aids approved by the expert panel established under section 4(b) for the medical care of the conditions described in subsection (g);

(ii) on expenditures for such conditions under the Medicare program, including a comparison of such expenditures for such conditions where such patient decision aids were used to such expenditures for such conditions where such patient decision aids were not used; and

(iii) on Medicare beneficiaries, including the understanding by beneficiaries of the options for medical care presented, concordance between beneficiary values and the medical care received, the mode of approved patient decision aid used (such as Internet, videos, and pamphlets), the tim-

ing of the delivery of such approved patient decision aid (such as the date of the initial diagnosis), and beneficiary and health care provider satisfaction with the shared decision making process;

(C) an evaluation of which eligible providers are most effective at implementing patient decision aids and assisting Medicare beneficiaries in making informed decisions on medical care; and

(D) recommendations for such legislation and administrative action as the Secretary determines appropriate.

(j) SAVINGS.—

(1) IN GENERAL.—Subject to paragraph (2), not later than 2 years after the implementation of phase I of the pilot program, and annually thereafter for the duration of phase I and the first 2 years of phase II, the Secretary shall determine if there were any savings to the Medicare program as a result of such implementation during the preceding year (or years, if applicable). In the case where the Secretary determines there were such savings, the Secretary shall use such savings as follows:

(A) Fifty percent of such savings shall be used to provide bonus payments to eligible providers participating in the pilot program who achieve high quality shared decision making (as measured by the level of participation of Medicare beneficiaries in the shared decision making process and high scores by the eligible provider on quality measures selected under subsection (h)(1)).

(B) Twenty-five percent of such savings shall be placed in a Shared Decision Making Trust Fund established by the Secretary, which shall be used to expand participation in the pilot program to providers of services and suppliers in additional settings (as determined appropriate by the Secretary) by—

(i) providing financial assistance under subsection (c); and

(ii) providing for the development of quality measures not already selected under subsection (h)(1) to assess the impact of shared decision making on the quality of patient care or the improvement of such quality measures already selected.

(C) Twenty-five percent of such savings shall be retained by the Medicare program.

(2) RETENTION OF SAVINGS BY THE MEDICARE PROGRAM.—In the case where the Secretary determines there are savings to the Medicare program as a result of the implementation of the pilot program during a year (beginning with the third year of phase II), 100 percent of such savings shall be retained by the Medicare program.

(k) WAIVER.—The Secretary may waive such provisions of titles XI and XVIII of the Social Security Act as may be necessary to carry out the pilot program under this section.

(l) FUNDING.—For purposes of carrying out section 4(a), implementing the pilot program under this section (including costs incurred in conducting the evaluation under subsection (i)), and carrying out section 1890(b)(1)(A)(iv) of the Social Security Act, as added by section 4(c), the Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i) to the Centers for Medicare & Medicaid Services Program Management Account of $300,000,000 for the period of fiscal years 2010 through 2017.

SEC. 6. ESTABLISHMENT OF SHARED DECISION MAKING STANDARDS AND REQUIREMENTS IN MEDICARE.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

''ESTABLISHMENT OF SHARED DECISION MAKING STANDARDS AND REQUIREMENTS

''SEC. 1899. (a) IN GENERAL.—Based on the findings of phases I and II of the pilot program under section 5 of the Empowering Medicare Patient Choices Act the Secretary shall promulgate regulations that—

''(1) specify for which preference sensitive conditions beneficiaries should, subject to the succeeding provisions of this section, participate in shared decision making;

''(2) require providers of services and suppliers to make sure that beneficiaries receive patient decision aids as appropriate; and

''(3) specify a process for beneficiaries to elect not to use such patient decision aids.

''(b) PENALTY FOR NOT USING SHARED DECISION MAKING.—Notwithstanding any other provision of this title, the Secretary shall promulgate such regulations and issue such guidance as may be necessary to reduce by 20 percent the amount of payment under this title that would

otherwise apply to an item or service specified by the Secretary if the patient does not receive a patient decision aid prior to such item or service being furnished (except in the case where the beneficiary has elected not to use such patient decision aid under the process specified under subsection (a)(3)).

''(c) SECRETARIAL AUTHORITY TO WAIVE APPLICATION OF THIS SECTION.—The Secretary may waive the application of this section to an item or service under this title if the Secretary determines either of the following:

''(1) Medical societies and others have established evidence-based transparent standards incorporating patient decision aids and shared decision making into the standard of patient care for preference sensitive conditions.

''(2) Shared decision making is not in the best interest of beneficiaries.''.

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