

111TH CONGRESS
1ST SESSION

S. 1133

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 SENATE OF THE UNITED STATES

MAY 21, 2009

Mr. WYDEN (for himself and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on Finance

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Empowering Medicare
5 Patient Choices Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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

6 (2) The Dartmouth Atlas Project has also
7 found that many clinical decisions physicians make
8 for elective medical treatments are driven by local
9 medical opinion, rather than sound science or the
10 preferences of well-informed patients. For example,
11 the Dartmouth Atlas Project found that, among the
12 306 Hospital Referral Regions in the United States
13 during the period of 2002 through 2003, the inci-
14 dence of surgery for back pain-related conditions
15 and joint replacement for chronic arthritis of the hip
16 and knee varied 5.9-, 5.6-, and 4.8-fold, respectively,
17 from the lowest to the highest region.

18 (3) Discretionary surgery for the following com-
19 mon conditions accounts for 40 percent of Medicare
20 spending for inpatient surgery: early stage cancer of
21 the prostate; early stage cancer of the breast; osteo-
22 arthritis of the knee; osteoarthritis of the hip; osteo-
23 arthritis of the spine; chest pain due to coronary ar-
24 tery disease; stroke threat from carotid artery dis-

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

3 (4) Decisions that involve values trade-offs be-
4 tween the benefits and harms of 2 or more clinically
5 appropriate alternatives should depend on the indi-
6 vidual patient's informed choice. In everyday prac-
7 tice, however, patients typically delegate decision
8 making to their physicians who may not have good
9 information on the patient's true preferences.

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

18 (6) Patient decision aids are tools designed to
19 help people participate in decision making about
20 health care options. Patient decision aids provide in-
21 formation on treatment options and help patients
22 clarify and communicate the personal value they as-
23 sociate with different features of treatment options.
24 Patient decision aids do not advise people to choose
25 one treatment option over another, nor are they

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

4 (7) The Lewin Group estimated that the change
 5 in spending resulting from the use of patient deci-
 6 sion aids for each of 11 conditions using per-proce-
 7 dure costs estimated for the Medicare population
 8 studied, assuming full implementation of such pa-
 9 tient decision aids in 2010, would save as much as
 10 \$4,000,000,000.

11 **SEC. 3. DEFINITIONS.**

12 In this Act:

13 (1) ELIGIBLE PROVIDER.—

14 (A) IN GENERAL.—The term “eligible pro-
 15 vider” means the following:

16 (i) A primary care practice.

17 (ii) A specialty practice.

18 (iii) A multispecialty group practice.

19 (iv) A hospital.

20 (v) A rural health clinic.

21 (vi) A Federally qualified health cen-
 22 ter (as defined in section 1861(aa)(4) of
 23 the Social Security Act (42 U.S.C.
 24 1395x(aa)(4)).

25 (vii) An integrated delivery system.

1 (viii) A State cooperative.

2 (B) INCLUSION OF MEDICARE ADVANTAGE
3 PLANS.—Such term includes a Medicare Advan-
4 tage plan offered by a Medicare Advantage or-
5 ganization under part C of title XVIII of the
6 Social Security Act (42 U.S.C. 1395w–21 et
7 seq.).

8 (2) PATIENT DECISION AID.—The term “pa-
9 tient decision aid” means an educational tool (such
10 as the Internet, a video, or a pamphlet) that helps
11 patients (or, if appropriate, the family caregiver of
12 the patient) understand and communicate their be-
13 liefs and preferences related to their treatment op-
14 tions, and to decide with their health care provider
15 what treatments are best for them based on their
16 treatment options, scientific evidence, circumstances,
17 beliefs, and preferences.

18 (3) PREFERENCE SENSITIVE CARE.—The term
19 “preference sensitive care” means medical care for
20 which the clinical evidence does not clearly support
21 one treatment option such that the appropriate
22 course of treatment depends on the values of the pa-
23 tient or the preferences of the patient regarding the
24 benefits, harms, and scientific evidence for each
25 treatment option. The use of such care should de-

1 pend on informed patient choice among clinically ap-
 2 propriate treatment options. Such term includes
 3 medical care for the conditions identified in section
 4 5(g).

5 (4) SECRETARY.—The term “Secretary” means
 6 the Secretary of Health and Human Services.

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

14 (6) STATE COOPERATIVE.—The term “State co-
 15 operative” means an entity that includes the State
 16 government and at least one other health care pro-
 17 vider which is set up for the purpose of testing
 18 shared decision making and patient decision aids.

19 **SEC. 4. ESTABLISHMENT OF INDEPENDENT STANDARDS**
 20 **FOR PATIENT DECISION AIDS.**

21 (a) CONTRACT WITH ENTITY TO ESTABLISH STAND-
 22 ARDS AND CERTIFY PATIENT DECISION AIDS.—

23 (1) CONTRACT.—

24 (A) IN GENERAL.—For purposes of sup-
 25 porting consensus-based standards for patient

1 decision aids and a certification process for pa-
2 tient decision aids for use in the Medicare pro-
3 gram and by other interested parties, the Sec-
4 retary shall identify and have in effect a con-
5 tract with an entity that meets the require-
6 ments described in paragraph (4). Such con-
7 tract shall provide that the entity perform the
8 duties described in paragraph (2).

9 (B) TIMING FOR FIRST CONTRACT.—As
10 soon as practicable after the date of the enact-
11 ment of this Act, the Secretary shall enter into
12 the first contract under subparagraph (A).

13 (C) PERIOD OF CONTRACT.—A contract
14 under subparagraph (A) shall be for a period of
15 18 months (except such contract may be re-
16 newed after a subsequent bidding process).

17 (D) COMPETITIVE PROCEDURES.—Com-
18 petitive procedures (as defined in section 4(5)
19 of the Office of Federal Procurement Policy Act
20 (41 U.S.C. 403(5))) shall be used to enter into
21 a contract under subparagraph (A).

22 (2) DUTIES.—The following duties are de-
23 scribed in this paragraph:

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

1 in an open and transparent manner and provide
2 the opportunity for public comment on the ac-
3 tivities described in subparagraphs (B) and (C).

4 (B) ESTABLISH STANDARDS FOR PATIENT
5 DECISION AIDS.—

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

14 (ii) DRAFT OF PROPOSED STAND-
15 ARDS.—The entity shall make a draft of
16 proposed standards available to the public.

17 (iii) 60-DAY COMMENT PERIOD.—Be-
18 ginning on the date the entity makes a
19 draft of the proposed standards available
20 under clause (ii), the entity shall provide a
21 60-day period for public comment on such
22 draft.

23 (iv) FINAL STANDARDS.—

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

1 subparagraph shall be adopted by the
2 board of the entity.

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

6 (C) CERTIFY PATIENT DECISION AIDS.—
7 The entity shall review patient decision aids
8 and certify whether patient decision aids meet
9 the standards established under subparagraph
10 (B) and offer a balanced presentation of treat-
11 ment options from both the clinical and patient
12 experience perspectives. In conducting such re-
13 view and certification, the entity shall give pri-
14 ority to the review and certification of patient
15 decision aids for conditions identified in section
16 5(g).

17 (3) REPORT TO THE EXPERT PANEL.—The en-
18 tity shall submit to the expert panel established
19 under subsection (b) a report on the standards es-
20 tablished for patient decision aids under paragraph
21 (2)(B) and patient decision aids that are certified as
22 meeting such standards under paragraph (2)(C).

23 (4) REQUIREMENTS DESCRIBED.—The fol-
24 lowing requirements are described in this paragraph:

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

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

6 (i) consumer engagement;

7 (ii) standard setting;

8 (iii) health literacy;

9 (iv) health care quality and safety
10 issues;

11 (v) certification processes;

12 (vi) measure development; and

13 (vii) evaluating health care quality.

14 (C) MEMBERSHIP FEES.—If the entity re-
15 quires a membership fee for participation in the
16 functions of the entity, such fees shall be rea-
17 sonable and adjusted based on the capacity of
18 the potential member to pay the fee. In no case
19 shall membership fees pose a barrier to the par-
20 ticipation of individuals or groups with low or
21 nominal resources to participate in the func-
22 tions of the entity.

23 (b) EXPERT PANEL.—

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

1 retary shall establish an expert panel to make rec-
2 ommendations to the Secretary regarding which pa-
3 tient decision aids should be implemented, appro-
4 priate training for health care providers on patient
5 decision aids and shared decision making, and ap-
6 propriate quality measures for use in the pilot pro-
7 gram under section 5 and under section 1899 of the
8 Social Security Act, as added by section 6.

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

11 (A) Approve patient decision aids, from
12 among those patient decision aids certified
13 under paragraph (2)(C) of subsection (a) by the
14 entity with a contract under such subsection,
15 for use in the pilot program under section 5
16 (including to the extent practicable, patient de-
17 cision aids for the medical care of the condi-
18 tions described in section 5(g) and under sec-
19 tion 1899 of the Social Security Act, as added
20 by section 6.

21 (B) Review current training curricula for
22 health care providers on patient decision aids
23 and shared decision making and recommend a
24 training process for eligible providers partici-
25 pating in the pilot program under section 5 on

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

3 (C) Review existing quality measures re-
4 garding patient knowledge, value concordance,
5 and health outcomes that have been endorsed
6 through a consensus-based process and rec-
7 ommend appropriate quality measures for selec-
8 tion under section 5(h)(1).

9 (3) APPOINTMENT.—The expert panel shall be
10 composed of 13 members appointed by the Secretary
11 from among leading experts in shared decision mak-
12 ing of whom—

13 (A) 2 shall be researchers;

14 (B) 2 shall be primary care physicians;

15 (C) 2 shall be from surgical specialties;

16 (D) 2 shall be patient or consumer commu-
17 nity advocates;

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

21 (F) 1 shall be from an integrated multispe-
22 cialty group practice;

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

1 (H) 1 shall be from the Centers for Dis-
2 ease Control and Prevention.

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

14 (5) TERMINATION.—The expert panel shall ter-
15minate on such date as the Secretary determines ap-
16propriate.

17 (c) QUALITY MEASURE DEVELOPMENT.—

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

21 (A) in clause (ii), by striking “and” at the
22 end; and

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

1 “(iv) that address conditions described
 2 in section 5(g) of the Empowering Medi-
 3 care Patient Choices Act and regional
 4 practice variations under this title; and”.

5 (2) CONFORMING AMENDMENT.—Section
 6 1890(d) of the Social Security Act (42 U.S.C.
 7 1395aaa(d)) is amended—

8 (A) by inserting “(other than subsection
 9 (b)(1)(A)(iv))” after “this section”; and

10 (B) by adding at the end the following new
 11 sentence: “For provisions relating to funding
 12 for the duties described in subsection
 13 (b)(1)(A)(iv), see section 5(l) of the Empow-
 14 ering Medicare Patient Choices Act.”.

15 **SEC. 5. ESTABLISHMENT OF SHARED DECISION MAKING**
 16 **PILOT PROGRAM UNDER THE MEDICARE**
 17 **PROGRAM.**

18 (a) IN GENERAL.—Not later than 12 months after
 19 the date of enactment of this Act, the Secretary shall es-
 20 tablish a pilot program to provide for the phased-in devel-
 21 opment, implementation, and evaluation of shared decision
 22 making under the Medicare program using patient deci-
 23 sion aids to meet the objective of improving the under-
 24 standing by Medicare beneficiaries of their medical treat-
 25 ment options, as compared to comparable Medicare bene-

1 ficiaries who do not participate in a shared decision mak-
2 ing process using patient decision aids.

3 (b) INITIAL IMPLEMENTATION (PHASE I).—

4 (1) IN GENERAL.—During the initial implemen-
5 tation of the pilot program under this section (re-
6 ferred to in this section as “phase I” of the pilot
7 program), the Secretary shall enroll in the pilot pro-
8 gram not more than 15 eligible providers who have
9 experience in implementing, and have invested in the
10 necessary infrastructure to implement, shared deci-
11 sion making using patient decision aids for a period
12 of 3 years.

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

18 (3) PREFERENCE.—In enrolling eligible pro-
19 viders in the pilot program during phase I, the Sec-
20 retary shall give preference to eligible providers
21 that—

22 (A) have documented experience in using
23 patient decision aids for the conditions identi-
24 fied in subsection (g) and in using shared deci-
25 sion making;

1 (B) have the necessary information tech-
2 nology infrastructure to collect the information
3 required by the Secretary for reporting pur-
4 poses;

5 (C) are trained in how to use patient deci-
6 sion aids and shared decision making; and

7 (D) would be eligible to receive financial
8 assistance as a Shared Decision Making Re-
9 source Center under subsection (c).

10 (c) SHARED DECISION MAKING RESOURCE CEN-
11 TERS.—

12 (1) IN GENERAL.—The Secretary shall provide
13 financial assistance for the establishment and sup-
14 port of Shared Decision Making Resource Centers
15 (referred to in this section as “centers”) to provide
16 technical assistance to eligible providers and to de-
17 velop and disseminate best practices and other infor-
18 mation to support and accelerate adoption, imple-
19 mentation, and effective use of patient decision aids
20 and shared decision making by eligible providers
21 under the Medicare program.

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

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

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

6 (A) providing assistance to eligible pro-
7 viders with the implementation and effective use
8 of, and training on, patient decision aids;

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

12 (C) providing assistance to eligible pro-
13 viders applying to participate or participating in
14 phase II of the pilot program under this section
15 or under section 1899 of the Social Security
16 Act, as added by section 6.

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

21 (A) Public or not-for-profit hospitals or
22 critical access hospitals (as defined in section
23 1861(mm)(1) of the Social Security Act (42
24 U.S.C. 1395x(mm)(1)).

1 (B) Federally qualified health centers (as
2 defined in section 1861(aa)(4) of the Social Se-
3 curity Act (42 U.S.C. 1395x(aa)(4)).

4 (C) Entities that are located in a rural
5 area or in area that serves uninsured, under-
6 insured, and medically underserved individuals
7 (regardless of whether such area is urban or
8 rural).

9 (D) Individual or small group practices (or
10 a consortium thereof) that are primarily fo-
11 cused on primary care.

12 (5) FINANCIAL ASSISTANCE.—

13 (A) IN GENERAL.—The Secretary may
14 provide financial assistance for a period of 8
15 years to any regional center established or sup-
16 ported under this subsection.

17 (B) COST-SHARING REQUIREMENT.—

18 (i) IN GENERAL.—Except as provided
19 in clause (ii), the Secretary shall not pro-
20 vide as financial assistance under this sub-
21 section more than 50 percent of the capital
22 and annual operating and maintenance
23 funds required to establish and support
24 such a center.

1 (ii) WAIVER OF COST-SHARING RE-
2 QUIREMENT.—The Secretary may waive
3 the limitation under clause (i) if the Sec-
4 retary determines that, as a result of na-
5 tional economic conditions, such limitation
6 would be detrimental to the pilot program
7 under this section. If the Secretary waives
8 such limitation under the preceding sen-
9 tence, the Secretary shall submit to Con-
10 gress a report containing the Secretary’s
11 justification for such waiver.

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

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

21 (B) Procedures to be followed by appli-
22 cants for financial assistance.

23 (C) Criteria for determining which appli-
24 cants are qualified to receive financial assist-
25 ance.

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

3 (7) APPLICATION REVIEW.—The Secretary shall
4 review each application for financial assistance
5 under this subsection based on merit. In making a
6 decision whether to approve such application and
7 provide financial assistance, the Secretary shall con-
8 sider at a minimum the merits of the application, in-
9 cluding those portions of the application regarding—

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

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

17 (C) the percentage of funding for the cen-
18 ter that would be provided as financial assist-
19 ance under this subsection and the amount of
20 any funding or in-kind commitment from
21 sources of funding in addition to the financial
22 assistance provided under this subsection.

23 (8) BIENNIAL EVALUATION.—Each center
24 which receives financial assistance under this sub-
25 section shall be evaluated biennially by an evaluation

1 panel appointed by the Secretary. Each such evalua-
2 tion panel shall be composed of private experts, none
3 of whom shall be connected with the center involved,
4 and officials of the Federal Government. Each eval-
5 uation panel shall measure the performance of the
6 center involved against the objectives specified in
7 paragraph (3). The Secretary shall not continue to
8 provide financial assistance to a center under this
9 subsection unless the most recent evaluation under
10 this paragraph with respect to the center is overall
11 positive.

12 (d) EXPANDED IMPLEMENTATION (PHASE II).—

13 (1) IN GENERAL.—Subject to paragraph (2),
14 during the 3-year period beginning after the comple-
15 tion of phase I of the pilot program (referred to in
16 this section as “phase II” of the pilot program), the
17 Secretary shall enroll additional eligible providers to
18 implement shared decision making using patient de-
19 cision aids under the pilot program under this sec-
20 tion. The Secretary may allow eligible providers to
21 enroll in the pilot program on a regular basis during
22 phase II.

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

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

5 (3) PREFERENCE.—In enrolling eligible pro-
6 viders in the pilot program during phase II, the Sec-
7 retary shall include, to the extent practicable, eligible
8 providers that—

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

14 (B) have training in the use of patient de-
15 cision aids or will participate in training for
16 health care professionals who will be involved in
17 such use (as specified by the Secretary); or

18 (C) represent high cost areas or high prac-
19 tice variation States under the Medicare pro-
20 gram, and the District of Columbia.

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

1 (f) REQUIREMENTS.—

2 (1) IMPLEMENTATION OF APPROVED PATIENT
3 DECISION AIDS.—

4 (A) IN GENERAL.—During phase II of the
5 pilot program under this section, an eligible
6 provider participating in the pilot program shall
7 incorporate 1 or more patient decision aids ap-
8 proved by the expert panel established under
9 section 4(b) in furnishing items and services to
10 Medicare beneficiaries with respect to 1 or more
11 of the conditions identified in subsection (g), to-
12 gether with ongoing support involved in fur-
13 nishing such items and services.

14 (B) DEFINED CLINICAL PROCESS.—During
15 each phase of the pilot program under this sec-
16 tion, the eligible provider shall establish and im-
17 plement a defined clinical process under which,
18 in the case of a Medicare beneficiary with 1 or
19 more of such conditions, the eligible provider of-
20 fers the Medicare beneficiary shared decision
21 making (supported by such a patient decision
22 aid) and collects information on the quality of
23 patient decision making with respect to the
24 Medicare beneficiary.

25 (2) FOLLOW-UP COUNSELING VISIT.—

1 (A) IN GENERAL.—During each phase of
2 the pilot program under this section, an eligible
3 provider participating in the pilot program
4 under this section shall routinely schedule Medi-
5 care beneficiaries for a counseling visit after the
6 viewing of such a patient decision aid to answer
7 any questions the beneficiary may have with re-
8 spect to the medical care of the condition in-
9 volved and to assist the beneficiary in thinking
10 through how their preferences and concerns re-
11 late to their medical care.

12 (B) PAYMENT FOR FOLLOW-UP COUN-
13 SELING VISIT.—The Secretary shall establish
14 procedures for making payments for such coun-
15 seling visits provided to Medicare beneficiaries
16 during each phase of the pilot program under
17 this section. Such procedures shall provide for
18 the establishment—

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

21 (ii) of a single payment amount for
22 such service that includes the professional
23 time of the health care provider and a por-
24 tion of the reasonable costs of the infra-
25 structure of the eligible provider.

1 (C) LIMITATION.—In the case of an eligi-
2 ble provider that is a Medicare Advantage plan,
3 such eligible provider may not receive payment
4 for such services.

5 (3) WAIVER OF COINSURANCE.—The Secretary
6 shall establish procedures under which an eligible
7 provider participating in the pilot program under
8 this section may, in the case of a low-income Medi-
9 care beneficiary (as determined by the Secretary),
10 waive any coinsurance or copayment that would oth-
11 erwise apply for the follow-up counseling visit pro-
12 vided to such Medicare beneficiary under paragraph
13 (2).

14 (4) COSTS OF IMPLEMENTATION.—

15 (A) IN GENERAL.—Subject to subpara-
16 graph (B), during each phase of the pilot pro-
17 gram, an eligible provider participating in the
18 pilot program shall be responsible for the costs
19 of selecting, purchasing, and incorporating such
20 patient decision aids into the group practice, re-
21 porting data on quality measures selected under
22 subsection (h)(1), and recording outcomes
23 under the pilot program.

24 (B) FINANCIAL SUPPORT.—During each
25 such phase, the Secretary may, in addition to

1 payments for counseling visits under paragraph
2 (2), provide financial support to an eligible pro-
3 vider participating in the pilot program to ac-
4 quire the infrastructure necessary to participate
5 in the pilot program, including the development
6 of clinical pathways to assure that Medicare
7 beneficiaries have access to high-quality shared
8 decision making, the reporting of data on qual-
9 ity measures selected under subsection (h)(1),
10 and the recording of outcomes under the pilot
11 program after phase I of the pilot program (as
12 determined appropriate by the Secretary).

13 (g) PREFERENCE SENSITIVE CARE DESCRIBED.—
14 The patient decision aids approved under section
15 4(b)(2)(A) shall, to the extent practicable, include patient
16 decision aids for medical care of the following conditions:

- 17 (1) Arthritis of the hip and knee.
- 18 (2) Chronic back pain.
- 19 (3) Chest pain (stable angina).
- 20 (4) Enlarged prostate (benign prostatic hyper-
21 trophy, or BPH).
- 22 (5) Early-stage prostate cancer.
- 23 (6) Early-stage breast cancer.
- 24 (7) End-of-life care.
- 25 (8) Peripheral vascular disease.

1 (9) Gall stones.

2 (10) Threat of stroke from carotid artery dis-
3 ease.

4 (11) Any other condition the Secretary identi-
5 fies as appropriate.

6 (h) QUALITY MEASURES.—

7 (1) SELECTION.—

8 (A) IN GENERAL.—During each phase of
9 the pilot program, the Secretary shall measure
10 the quality and implementation of shared deci-
11 sion making. For purposes of making such
12 measurements, the Secretary shall select, from
13 among those quality measures recommended by
14 the expert panel under section 4(b)(2)(C), con-
15 sensus-based quality measures that assess
16 Medicare beneficiaries' knowledge of the options
17 for medical treatment relevant to their medical
18 condition, as well as the benefits and drawbacks
19 of those medical treatment options, and the
20 Medicare beneficiaries' goals and concerns re-
21 garding their medical care.

22 (B) RISK ADJUSTMENT.—In order to en-
23 sure accurate measurement across quality
24 measures and eligible providers, the Secretary
25 may risk adjust the quality measures selected

1 under this paragraph to control for external
2 factors, such as cognitive impairment, demen-
3 tia, and literacy.

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

10 (3) FEEDBACK ON MEASURES.—During each
11 such phase, the Secretary shall provide confidential
12 reports to eligible providers participating in the pilot
13 program on the performance of the eligible provider
14 on quality measures selected by the Secretary under
15 paragraph (1), the aggregate performance of all eli-
16 gible providers participating in the pilot program,
17 and any improvements in such performance.

18 (i) EVALUATIONS AND REPORTS.—

19 (1) INDEPENDENT EVALUATION.—The Sec-
20 retary shall enter into a contract with an entity that
21 has knowledge of shared decision making programs
22 and demonstrated experience in the evaluation of
23 such programs for the conduct of an independent
24 evaluation of each phase of the pilot program under
25 this section.

1 (2) REPORTS BY ENTITY CONDUCTING INDE-
2 PENDENT EVALUATION.—

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

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

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

16 (i) include an assessment of—

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

19 (II) Medicare beneficiary and
20 health care provider satisfaction under
21 the applicable phase of the pilot pro-
22 gram;

23 (III) utilization of medical serv-
24 ices for Medicare beneficiaries with 1
25 or more of the conditions described in

1 subsection (g) and other Medicare
2 beneficiaries as determined appro-
3 priate by the Secretary;

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

8 (V) savings to the Medicare pro-
9 gram under title XVIII of the Social
10 Security Act; and

11 (VI) the costs to eligible pro-
12 viders participating in the pilot pro-
13 gram of selecting, purchasing, and in-
14 corporating approved patient decision
15 aids and meeting reporting require-
16 ments under the applicable phase of
17 the pilot program; and

18 (ii) identify the characteristics of indi-
19 vidual eligible providers that are most ef-
20 fective in implementing shared decision
21 making under the applicable phase of the
22 pilot program.

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

1 Congress a report on the pilot program that in-
2 cludes—

3 (A) the results of the independent evalua-
4 tion conducted under paragraph (2);

5 (B) an evaluation of the impact of the pilot
6 program under this section, including the im-
7 pact—

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

12 (ii) on expenditures for such condi-
13 tions under the Medicare program, includ-
14 ing a comparison of such expenditures for
15 such conditions where such patient deci-
16 sion aids were used to such expenditures
17 for such conditions where such patient de-
18 cision aids were not used; and

19 (iii) on Medicare beneficiaries, includ-
20 ing the understanding by beneficiaries of
21 the options for medical care presented,
22 concordance between beneficiary values
23 and the medical care received, the mode of
24 approved patient decision aid used (such as
25 Internet, videos, and pamphlets), the tim-

1 ing of the delivery of such approved patient
2 decision aid (such as the date of the initial
3 diagnosis), and beneficiary and health care
4 provider satisfaction with the shared deci-
5 sion making process;

6 (C) an evaluation of which eligible pro-
7 viders are most effective at implementing pa-
8 tient decision aids and assisting Medicare bene-
9 ficiaries in making informed decisions on med-
10 ical care; and

11 (D) recommendations for such legislation
12 and administrative action as the Secretary de-
13 termines appropriate.

14 (j) SAVINGS.—

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

1 (A) Fifty percent of such savings shall be
2 used to provide bonus payments to eligible pro-
3 viders participating in the pilot program who
4 achieve high quality shared decision making (as
5 measured by the level of participation of Medi-
6 care beneficiaries in the shared decision making
7 process and high scores by the eligible provider
8 on quality measures selected under subsection
9 (h)(1)).

10 (B) Twenty-five percent of such savings
11 shall be placed in a Shared Decision Making
12 Trust Fund established by the Secretary, which
13 shall be used to expand participation in the
14 pilot program to providers of services and sup-
15 pliers in additional settings (as determined ap-
16 propriate by the Secretary) by—

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

19 (ii) providing for the development of
20 quality measures not already selected
21 under subsection (h)(1) to assess the im-
22 pact of shared decision making on the
23 quality of patient care or the improvement
24 of such quality measures already selected.

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

3 (2) RETENTION OF SAVINGS BY THE MEDICARE
4 PROGRAM.—In the case where the Secretary deter-
5 mines there are savings to the Medicare program as
6 a result of the implementation of the pilot program
7 during a year (beginning with the third year of
8 phase II), 100 percent of such savings shall be re-
9 tained by the Medicare program.

10 (k) WAIVER.—The Secretary may waive such provi-
11 sions of titles XI and XVIII of the Social Security Act
12 as may be necessary to carry out the pilot program under
13 this section.

14 (l) FUNDING.—For purposes of carrying out section
15 4(a), implementing the pilot program under this section
16 (including costs incurred in conducting the evaluation
17 under subsection (i)), and carrying out section
18 1890(b)(1)(A)(iv) of the Social Security Act, as added by
19 section 4(c), the Secretary shall provide for the transfer
20 from the Federal Hospital Insurance Trust Fund estab-
21 lished under section 1817 of the Social Security Act (42
22 U.S.C. 1395i) to the Centers for Medicare & Medicaid
23 Services Program Management Account of \$300,000,000
24 for the period of fiscal years 2010 through 2017.

1 **SEC. 6. ESTABLISHMENT OF SHARED DECISION MAKING**
 2 **STANDARDS AND REQUIREMENTS IN MEDI-**
 3 **CARE.**

4 Title XVIII of the Social Security Act (42 U.S.C.
 5 1395 et seq.) is amended by adding at the end the fol-
 6 lowing new section:

7 “ESTABLISHMENT OF SHARED DECISION MAKING
 8 STANDARDS AND REQUIREMENTS

9 “SEC. 1899. (a) IN GENERAL.—Based on the find-
 10 ings of phases I and II of the pilot program under section
 11 5 of the Empowering Medicare Patient Choices Act the
 12 Secretary shall promulgate regulations that—

13 “(1) specify for which preference sensitive con-
 14 ditions beneficiaries should, subject to the suc-
 15 ceeding provisions of this section, participate in
 16 shared decision making;

17 “(2) require providers of services and suppliers
 18 to make sure that beneficiaries receive patient deci-
 19 sion aids as appropriate; and

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

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

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

7 “(c) SECRETARIAL AUTHORITY TO WAIVE APPLICA-
8 TION OF THIS SECTION.—The Secretary may waive the
9 application of this section to an item or service under this
10 title if the Secretary determines either of the following:

11 “(1) Medical societies and others have estab-
12 lished evidence-based transparent standards incor-
13 porating patient decision aids and shared decision
14 making into the standard of patient care for pref-
15 erence sensitive conditions.

16 “(2) Shared decision making is not in the best
17 interest of beneficiaries.”.

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