



1       **(b) CONFORMING AMENDMENT.**—Section 6001(b)(2) of  
2 *this Act is amended by striking “November 1, 2011” and*  
3 *inserting “May 1, 2012”.*

4 **SEC. 10602. CLARIFICATIONS TO PATIENT-CENTERED OUT-**  
5 **COMES RESEARCH.**

6       Section 1181 of the Social Security Act (as added by  
7 section 6301) is amended—

8           (1) in subsection (d)(2)(B)—

9               (A) in clause (ii)(IV)—

10                   (i) by inserting “, as described in sub-  
11 paragraph (A)(i),” after “original re-  
12 search”; and

13                   (ii) by inserting “, as long as the re-  
14 searcher enters into a data use agreement  
15 with the Institute for use of the data from  
16 the original research, as appropriate” after  
17 “publication”; and

18               (B) by amending clause (iv) to read as fol-  
19 lows:

20                   “(iv) **SUBSEQUENT USE OF THE**  
21 **DATA.**—The Institute shall not allow the  
22 subsequent use of data from original re-  
23 search in work-for-hire contracts with indi-  
24 viduals, entities, or instrumentalities that  
25 have a financial interest in the results, un-

1           less approved under a data use agreement  
2           with the Institute.”;

3           (2) in subsection (d)(8)(A)(iv), by striking “not  
4           be construed as mandates for” and inserting “do not  
5           include”; and

6           (3) in subsection (f)(1)(C), by amending clause  
7           (ii) to read as follows:

8                   “(ii) 7 members representing physi-  
9                   cians and providers, including 4 members  
10                   representing physicians (at least 1 of whom  
11                   is a surgeon), 1 nurse, 1 State-licensed inte-  
12                   grative health care practitioner, and 1 rep-  
13                   resentative of a hospital.”.

14 **SEC. 10603. STRIKING PROVISIONS RELATING TO INDI-**  
15 **VIDUAL PROVIDER APPLICATION FEES.**

16           (a) *IN GENERAL.*—Section 1866(j)(2)(C) of the Social  
17 Security Act, as added by section 6401(a), is amended—

18                   (1) by striking clause (i);

19                   (2) by redesignating clauses (ii) through (iv), re-  
20                   spectively, as clauses (i) through (iii); and

21                   (3) in clause (i), as redesignated by paragraph  
22                   (2), by striking “clause (iii)” and inserting “clause  
23                   (ii)”.

24           (b) *TECHNICAL CORRECTION.*—Section 6401(a)(2) of  
25 this Act is amended to read as follows:

1           “(2) by redesignating paragraph (2) as para-  
2           graph (8); and”.

3 **SEC. 10604. TECHNICAL CORRECTION TO SECTION 6405.**

4           *Paragraphs (1) and (2) of section 6405(b) are amend-*  
5 *ed to read as follows:*

6           “(1) *PART A.—Section 1814(a)(2) of the Social*  
7 *Security Act (42 U.S.C. 1395(a)(2)) is amended in*  
8 *the matter preceding subparagraph (A) by inserting*  
9 *‘, or, in the case of services described in subparagraph*  
10 *(C), a physician enrolled under section 1866(j),’ after*  
11 *‘in collaboration with a physician,’.*

12           “(2) *PART B.—Section 1835(a)(2) of the Social*  
13 *Security Act (42 U.S.C. 1395n(a)(2)) is amended in*  
14 *the matter preceding subparagraph (A) by inserting*  
15 *‘, or, in the case of services described in subparagraph*  
16 *(A), a physician enrolled under section 1866(j),’ after*  
17 *‘a physician.’.*”.

18 **SEC. 10605. CERTAIN OTHER PROVIDERS PERMITTED TO**  
19 **CONDUCT FACE TO FACE ENCOUNTER FOR**  
20 **HOME HEALTH SERVICES.**

21           *(a) PART A.—Section 1814(a)(2)(C) of the Social Se-*  
22 *curity Act (42 U.S.C. 1395f(a)(2)(C)), as amended by sec-*  
23 *tion 6407(a)(1), is amended by inserting “, or a nurse prac-*  
24 *titioner or clinical nurse specialist (as those terms are de-*  
25 *fin ed in section 1861(aa)(5)) who is working in collabora-*

1 *tion with the physician in accordance with State law, or*  
2 *a certified nurse-midwife (as defined in section 1861(gg))*  
3 *as authorized by State law, or a physician assistant (as*  
4 *defined in section 1861(aa)(5)) under the supervision of the*  
5 *physician,” after “himself or herself”.*

6 (b) *PART B.—Section 1835(a)(2)(A)(iv) of the Social*  
7 *Security Act, as added by section 6407(a)(2), is amended*  
8 *by inserting “, or a nurse practitioner or clinical nurse spe-*  
9 *cialist (as those terms are defined in section 1861(aa)(5))*  
10 *who is working in collaboration with the physician in ac-*  
11 *cordance with State law, or a certified nurse-midwife (as*  
12 *defined in section 1861(gg)) as authorized by State law, or*  
13 *a physician assistant (as defined in section 1861(aa)(5))*  
14 *under the supervision of the physician,” after “must docu-*  
15 *ment that the physician”.*

16 **SEC. 10606. HEALTH CARE FRAUD ENFORCEMENT.**

17 (a) *FRAUD SENTENCING GUIDELINES.—*

18 (1) *DEFINITION.—In this subsection, the term*  
19 *“Federal health care offense” has the meaning given*  
20 *that term in section 24 of title 18, United States*  
21 *Code, as amended by this Act.*

22 (2) *REVIEW AND AMENDMENTS.—Pursuant to*  
23 *the authority under section 994 of title 28, United*  
24 *States Code, and in accordance with this subsection,*  
25 *the United States Sentencing Commission shall—*

1           (A) review the Federal Sentencing Guide-  
2 lines and policy statements applicable to persons  
3 convicted of Federal health care offenses;

4           (B) amend the Federal Sentencing Guide-  
5 lines and policy statements applicable to persons  
6 convicted of Federal health care offenses involv-  
7 ing Government health care programs to provide  
8 that the aggregate dollar amount of fraudulent  
9 bills submitted to the Government health care  
10 program shall constitute prima facie evidence of  
11 the amount of the intended loss by the defendant;  
12 and

13           (C) amend the Federal Sentencing Guide-  
14 lines to provide—

15                 (i) a 2-level increase in the offense level  
16 for any defendant convicted of a Federal  
17 health care offense relating to a Government  
18 health care program which involves a loss of  
19 not less than \$1,000,000 and less than  
20 \$7,000,000;

21                 (ii) a 3-level increase in the offense  
22 level for any defendant convicted of a Fed-  
23 eral health care offense relating to a Gov-  
24 ernment health care program which involves

1           *a loss of not less than \$7,000,000 and less*  
2           *than \$20,000,000;*

3           *(iii) a 4-level increase in the offense*  
4           *level for any defendant convicted of a Fed-*  
5           *eral health care offense relating to a Gov-*  
6           *ernment health care program which involves*  
7           *a loss of not less than \$20,000,000; and*

8           *(iv) if appropriate, otherwise amend*  
9           *the Federal Sentencing Guidelines and pol-*  
10          *icy statements applicable to persons con-*  
11          *victed of Federal health care offenses involv-*  
12          *ing Government health care programs.*

13          (3) *REQUIREMENTS.—In carrying this sub-*  
14          *section, the United States Sentencing Commission*  
15          *shall—*

16                 (A) *ensure that the Federal Sentencing*  
17                 *Guidelines and policy statements—*

18                         (i) *reflect the serious harms associated*  
19                         *with health care fraud and the need for ag-*  
20                         *gressive and appropriate law enforcement*  
21                         *action to prevent such fraud; and*

22                         (ii) *provide increased penalties for per-*  
23                         *sons convicted of health care fraud offenses*  
24                         *in appropriate circumstances;*

1           (B) consult with individuals or groups rep-  
2           resenting health care fraud victims, law enforce-  
3           ment officials, the health care industry, and the  
4           Federal judiciary as part of the review described  
5           in paragraph (2);

6           (C) ensure reasonable consistency with other  
7           relevant directives and with other guidelines  
8           under the Federal Sentencing Guidelines;

9           (D) account for any aggravating or miti-  
10          gating circumstances that might justify excep-  
11          tions, including circumstances for which the Fed-  
12          eral Sentencing Guidelines, as in effect on the  
13          date of enactment of this Act, provide sentencing  
14          enhancements;

15          (E) make any necessary conforming changes  
16          to the Federal Sentencing Guidelines; and

17          (F) ensure that the Federal Sentencing  
18          Guidelines adequately meet the purposes of sen-  
19          tencing.

20          (b) *INTENT REQUIREMENT FOR HEALTH CARE*  
21 *FRAUD.*—Section 1347 of title 18, United States Code, is  
22 amended—

23           (1) by inserting “(a)” before “Whoever know-  
24           ingly”; and

25           (2) by adding at the end the following:

1       “(b) *With respect to violations of this section, a person*  
2 *need not have actual knowledge of this section or specific*  
3 *intent to commit a violation of this section.*”.

4       (c) *HEALTH CARE FRAUD OFFENSE.—Section 24(a)*  
5 *of title 18, United States Code, is amended—*

6           (1) *in paragraph (1), by striking the semicolon*  
7 *and inserting “or section 1128B of the Social Secu-*  
8 *urity Act (42 U.S.C. 1320a–7b); or”;* and

9           (2) *in paragraph (2)—*

10           (A) *by inserting “1349,” after “1343,”; and*

11           (B) *by inserting “section 301 of the Federal*  
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 331),*  
13 *or section 501 of the Employee Retirement In-*  
14 *come Security Act of 1974 (29 U.S.C. 1131),”*  
15 *after “title.”.*

16       (d) *SUBPOENA AUTHORITY RELATING TO HEALTH*  
17 *CARE.—*

18           (1) *SUBPOENAS UNDER THE HEALTH INSURANCE*  
19 *PORTABILITY AND ACCOUNTABILITY ACT OF 1996.—*  
20 *Section 1510(b) of title 18, United States Code, is*  
21 *amended—*

22           (A) *in paragraph (1), by striking “to the*  
23 *grand jury”;* and

24           (B) *in paragraph (2)—*

1                   (i) in subparagraph (A), by striking  
2                   “grand jury subpoena” and inserting “sub-  
3                   poena for records”; and

4                   (ii) in the matter following subpara-  
5                   graph (B), by striking “to the grand jury”.

6                   (2) *SUBPOENAS UNDER THE CIVIL RIGHTS OF IN-*  
7                   *STITUTIONALIZED PERSONS ACT.—The Civil Rights of*  
8                   *Institutionalized Persons Act (42 U.S.C. 1997 et seq.)*  
9                   *is amended by inserting after section 3 the following:*

10                   **“SEC. 3A. SUBPOENA AUTHORITY.**

11                   “(a) **AUTHORITY.**—The Attorney General, or at the  
12                   direction of the Attorney General, any officer or employee  
13                   of the Department of Justice may require by subpoena  
14                   access to any institution that is the subject of an investiga-  
15                   tion under this Act and to any document, record, material,  
16                   file, report, memorandum, policy, procedure, investigation,  
17                   video or audio recording, or quality assurance report relat-  
18                   ing to any institution that is the subject of an investiga-  
19                   tion under this Act to determine whether there are condi-  
20                   tions which deprive persons residing in or confined to the  
21                   institution of any rights, privileges, or immunities secured  
22                   or protected by the Constitution or laws of the United  
23                   States.

24                   “(b) **ISSUANCE AND ENFORCEMENT OF SUB-**  
25                   **POENAS.**—

1           “(1) ISSUANCE.—Subpoenas issued under this  
2 section—

3           “(A) shall bear the signature of the Attor-  
4 ney General or any officer or employee of the  
5 Department of Justice as designated by the At-  
6 torney General; and

7           “(B) shall be served by any person or class  
8 of persons designated by the Attorney General  
9 or a designated officer or employee for that  
10 purpose.

11           “(2) ENFORCEMENT.—In the case of contu-  
12 macy or failure to obey a subpoena issued under this  
13 section, the United States district court for the judi-  
14 cial district in which the institution is located may  
15 issue an order requiring compliance. Any failure to  
16 obey the order of the court may be punished by the  
17 court as a contempt that court.

18           “(c) *PROTECTION OF SUBPOENAED RECORDS AND IN-*  
19 *FORMATION.—Any document, record, material, file, report,*  
20 *memorandum, policy, procedure, investigation, video or*  
21 *audio recording, or quality assurance report or other infor-*  
22 *mation obtained under a subpoena issued under this sec-*  
23 *tion—*

24           “(1) *may not be used for any purpose other than*  
25 *to protect the rights, privileges, or immunities secured*

1       *or protected by the Constitution or laws of the United*  
2       *States of persons who reside, have resided, or will re-*  
3       *side in an institution;*

4               “(2) *may not be transmitted by or within the*  
5       *Department of Justice for any purpose other than to*  
6       *protect the rights, privileges, or immunities secured or*  
7       *protected by the Constitution or laws of the United*  
8       *States of persons who reside, have resided, or will re-*  
9       *side in an institution; and*

10              “(3) *shall be redacted, obscured, or otherwise al-*  
11       *tered if used in any publicly available manner so as*  
12       *to prevent the disclosure of any personally identifiable*  
13       *information.”.*

14   **SEC. 10607. STATE DEMONSTRATION PROGRAMS TO EVALU-**  
15                    **ATE ALTERNATIVES TO CURRENT MEDICAL**  
16                    **TORT LITIGATION.**

17       *Part P of title III of the Public Health Service Act*  
18       *(42 U.S.C. 280g et seq.), as amended by this Act, is further*  
19       *amended by adding at the end the following:*

20   **“SEC. 399V-4. STATE DEMONSTRATION PROGRAMS TO**  
21                    **EVALUATE ALTERNATIVES TO CURRENT MED-**  
22                    **ICAL TORT LITIGATION.**

23              “(a) *IN GENERAL.—The Secretary is authorized to*  
24       *award demonstration grants to States for the development,*  
25       *implementation, and evaluation of alternatives to current*

1 *tort litigation for resolving disputes over injuries allegedly*  
2 *caused by health care providers or health care organiza-*  
3 *tions. In awarding such grants, the Secretary shall ensure*  
4 *the diversity of the alternatives so funded.*

5 “(b) *DURATION.—The Secretary may award grants*  
6 *under subsection (a) for a period not to exceed 5 years.*

7 “(c) *CONDITIONS FOR DEMONSTRATION GRANTS.—*

8 “(1) *REQUIREMENTS.—Each State desiring a*  
9 *grant under subsection (a) shall develop an alter-*  
10 *native to current tort litigation that—*

11 “(A) *allows for the resolution of disputes*  
12 *over injuries allegedly caused by health care pro-*  
13 *viders or health care organizations; and*

14 “(B) *promotes a reduction of health care er-*  
15 *rors by encouraging the collection and analysis*  
16 *of patient safety data related to disputes resolved*  
17 *under subparagraph (A) by organizations that*  
18 *engage in efforts to improve patient safety and*  
19 *the quality of health care.*

20 “(2) *ALTERNATIVE TO CURRENT TORT LITIGA-*  
21 *TION.—Each State desiring a grant under subsection*  
22 *(a) shall demonstrate how the proposed alternative de-*  
23 *scribed in paragraph (1)(A)—*

1           “(A) makes the medical liability system  
2 more reliable by increasing the availability of  
3 prompt and fair resolution of disputes;

4           “(B) encourages the efficient resolution of  
5 disputes;

6           “(C) encourages the disclosure of health care  
7 errors;

8           “(D) enhances patient safety by detecting,  
9 analyzing, and helping to reduce medical errors  
10 and adverse events;

11           “(E) improves access to liability insurance;

12           “(F) fully informs patients about the dif-  
13 ferences in the alternative and current tort liti-  
14 gation;

15           “(G) provides patients the ability to opt out  
16 of or voluntarily withdraw from participating in  
17 the alternative at any time and to pursue other  
18 options, including litigation, outside the alter-  
19 native;

20           “(H) would not conflict with State law at  
21 the time of the application in a way that would  
22 prohibit the adoption of an alternative to current  
23 tort litigation; and

24           “(I) would not limit or curtail a patient’s  
25 existing legal rights, ability to file a claim in or

1           *access a State’s legal system, or otherwise abro-*  
2           *gate a patient’s ability to file a medical mal-*  
3           *practice claim.*

4           “(3) *SOURCES OF COMPENSATION.*—*Each State*  
5           *desiring a grant under subsection (a) shall identify*  
6           *the sources from and methods by which compensation*  
7           *would be paid for claims resolved under the proposed*  
8           *alternative to current tort litigation, which may in-*  
9           *clude public or private funding sources, or a com-*  
10          *bination of such sources. Funding methods shall to the*  
11          *extent practicable provide financial incentives for ac-*  
12          *tivities that improve patient safety.*

13          “(4) *SCOPE.*—

14                 “(A) *IN GENERAL.*—*Each State desiring a*  
15                 *grant under subsection (a) shall establish a scope*  
16                 *of jurisdiction (such as Statewide, designated ge-*  
17                 *ographic region, a designated area of health care*  
18                 *practice, or a designated group of health care*  
19                 *providers or health care organizations) for the*  
20                 *proposed alternative to current tort litigation*  
21                 *that is sufficient to evaluate the effects of the al-*  
22                 *ternative. No scope of jurisdiction shall be estab-*  
23                 *lished under this paragraph that is based on a*  
24                 *health care payer or patient population.*

1           “(B) *NOTIFICATION OF PATIENTS.*—A State  
2           shall demonstrate how patients would be notified  
3           that they are receiving health care services that  
4           fall within such scope, and the process by which  
5           they may opt out of or voluntarily withdraw  
6           from participating in the alternative. The deci-  
7           sion of the patient whether to participate or con-  
8           tinue participating in the alternative process  
9           shall be made at any time and shall not be lim-  
10          ited in any way.

11          “(5) *PREFERENCE IN AWARDING DEMONSTRATION GRANTS.*—In awarding grants under subsection  
12          (a), the Secretary shall give preference to States—

14                 “(A) that have developed the proposed alter-  
15                 native through substantive consultation with rel-  
16                 evant stakeholders, including patient advocates,  
17                 health care providers and health care organiza-  
18                 tions, attorneys with expertise in representing  
19                 patients and health care providers, medical mal-  
20                 practice insurers, and patient safety experts;

21                 “(B) that make proposals that are likely to  
22                 enhance patient safety by detecting, analyzing,  
23                 and helping to reduce medical errors and adverse  
24                 events; and

1           “(C) that make proposals that are likely to  
2           improve access to liability insurance.

3           “(d) APPLICATION.—

4           “(1) IN GENERAL.—Each State desiring a grant  
5           under subsection (a) shall submit to the Secretary an  
6           application, at such time, in such manner, and con-  
7           taining such information as the Secretary may re-  
8           quire.

9           “(2) REVIEW PANEL.—

10           “(A) IN GENERAL.—In reviewing applica-  
11           tions under paragraph (1), the Secretary shall  
12           consult with a review panel composed of relevant  
13           experts appointed by the Comptroller General.

14           “(B) COMPOSITION.—

15           “(i) NOMINATIONS.—The Comptroller  
16           General shall solicit nominations from the  
17           public for individuals to serve on the review  
18           panel.

19           “(ii) APPOINTMENT.—The Comptroller  
20           General shall appoint, at least 9 but not  
21           more than 13, highly qualified and knowl-  
22           edgeable individuals to serve on the review  
23           panel and shall ensure that the following  
24           entities receive fair representation on such  
25           panel:

1                   “(I) *Patient advocates.*

2                   “(II) *Health care providers and*  
3                   *health care organizations.*

4                   “(III) *Attorneys with expertise in*  
5                   *representing patients and health care*  
6                   *providers.*

7                   “(IV) *Medical malpractice insur-*  
8                   *ers.*

9                   “(V) *State officials.*

10                  “(VI) *Patient safety experts.*

11                  “(C) *CHAIRPERSON.—The Comptroller Gen-*  
12                  *eral, or an individual within the Government*  
13                  *Accountability Office designated by the Comp-*  
14                  *troller General, shall be the chairperson of the re-*  
15                  *view panel.*

16                  “(D) *AVAILABILITY OF INFORMATION.—The*  
17                  *Comptroller General shall make available to the*  
18                  *review panel such information, personnel, and*  
19                  *administrative services and assistance as the re-*  
20                  *view panel may reasonably require to carry out*  
21                  *its duties.*

22                  “(E) *INFORMATION FROM AGENCIES.—The*  
23                  *review panel may request directly from any de-*  
24                  *partment or agency of the United States any in-*  
25                  *formation that such panel considers necessary to*

1           *carry out its duties. To the extent consistent with*  
2           *applicable laws and regulations, the head of such*  
3           *department or agency shall furnish the requested*  
4           *information to the review panel.*

5           “(e) *REPORTS.*—

6           “(1) *BY STATE.*—*Each State receiving a grant*  
7           *under subsection (a) shall submit to the Secretary an*  
8           *annual report evaluating the effectiveness of activities*  
9           *funded with grants awarded under such subsection.*  
10          *Such report shall, at a minimum, include the impact*  
11          *of the activities funded on patient safety and on the*  
12          *availability and price of medical liability insurance.*

13          “(2) *BY SECRETARY.*—*The Secretary shall sub-*  
14          *mit to Congress an annual compendium of the reports*  
15          *submitted under paragraph (1) and an analysis of*  
16          *the activities funded under subsection (a) that exam-*  
17          *ines any differences that result from such activities in*  
18          *terms of the quality of care, number and nature of*  
19          *medical errors, medical resources used, length of time*  
20          *for dispute resolution, and the availability and price*  
21          *of liability insurance.*

22          “(f) *TECHNICAL ASSISTANCE.*—

23          “(1) *IN GENERAL.*—*The Secretary shall provide*  
24          *technical assistance to the States applying for or*  
25          *awarded grants under subsection (a).*

1           “(2) *REQUIREMENTS.—Technical assistance*  
2 *under paragraph (1) shall include—*

3           “(A) *guidance on non-economic damages,*  
4 *including the consideration of individual facts*  
5 *and circumstances in determining appropriate*  
6 *payment, guidance on identifying avoidable in-*  
7 *juries, and guidance on disclosure to patients of*  
8 *health care errors and adverse events; and*

9           “(B) *the development, in consultation with*  
10 *States, of common definitions, formats, and data*  
11 *collection infrastructure for States receiving*  
12 *grants under this section to use in reporting to*  
13 *facilitate aggregation and analysis of data both*  
14 *within and between States.*

15           “(3) *USE OF COMMON DEFINITIONS, FORMATS,*  
16 *AND DATA COLLECTION INFRASTRUCTURE.—States*  
17 *not receiving grants under this section may also use*  
18 *the common definitions, formats, and data collection*  
19 *infrastructure developed under paragraph (2)(B).*

20           “(g) *EVALUATION.—*

21           “(1) *IN GENERAL.—The Secretary, in consulta-*  
22 *tion with the review panel established under sub-*  
23 *section (d)(2), shall enter into a contract with an ap-*  
24 *propriate research organization to conduct an overall*  
25 *evaluation of the effectiveness of grants awarded*

1 *under subsection (a) and to annually prepare and*  
2 *submit a report to Congress. Such an evaluation shall*  
3 *begin not later than 18 months following the date of*  
4 *implementation of the first program funded by a*  
5 *grant under subsection (a).*

6 “(2) *CONTENTS.—The evaluation under para-*  
7 *graph (1) shall include—*

8 “(A) *an analysis of the effects of the grants*  
9 *awarded under subsection (a) with regard to the*  
10 *measures described in paragraph (3);*

11 “(B) *for each State, an analysis of the ex-*  
12 *tent to which the alternative developed under*  
13 *subsection (c)(1) is effective in meeting the ele-*  
14 *ments described in subsection (c)(2);*

15 “(C) *a comparison among the States receiv-*  
16 *ing grants under subsection (a) of the effective-*  
17 *ness of the various alternatives developed by such*  
18 *States under subsection (c)(1);*

19 “(D) *a comparison, considering the meas-*  
20 *ures described in paragraph (3), of States receiv-*  
21 *ing grants approved under subsection (a) and*  
22 *similar States not receiving such grants; and*

23 “(E) *a comparison, with regard to the*  
24 *measures described in paragraph (3), of—*

1           “(i) States receiving grants under sub-  
2           section (a);

3           “(ii) States that enacted, prior to the  
4           date of enactment of the Patient Protection  
5           and Affordable Care Act, any cap on non-  
6           economic damages; and

7           “(iii) States that have enacted, prior to  
8           the date of enactment of the Patient Protec-  
9           tion and Affordable Care Act, a requirement  
10          that the complainant obtain an opinion re-  
11          garding the merit of the claim, although the  
12          substance of such opinion may have no  
13          bearing on whether the complainant may  
14          proceed with a case.

15          “(3) MEASURES.—The evaluations under para-  
16          graph (2) shall analyze and make comparisons on the  
17          basis of—

18                 “(A) the nature and number of disputes  
19                 over injuries allegedly caused by health care pro-  
20                 viders or health care organizations;

21                 “(B) the nature and number of claims in  
22                 which tort litigation was pursued despite the ex-  
23                 istence of an alternative under subsection (a);

1           “(C) *the disposition of disputes and claims,*  
2           *including the length of time and estimated costs*  
3           *to all parties;*

4           “(D) *the medical liability environment;*

5           “(E) *health care quality;*

6           “(F) *patient safety in terms of detecting,*  
7           *analyzing, and helping to reduce medical errors*  
8           *and adverse events;*

9           “(G) *patient and health care provider and*  
10          *organization satisfaction with the alternative*  
11          *under subsection (a) and with the medical liabil-*  
12          *ity environment; and*

13          “(H) *impact on utilization of medical serv-*  
14          *ices, appropriately adjusted for risk.*

15          “(4) *FUNDING.—The Secretary shall reserve 5*  
16          *percent of the amount appropriated in each fiscal*  
17          *year under subsection (k) to carry out this subsection.*

18          “(h) *MEDPAC AND MACPAC REPORTS.—*

19                 “(1) *MEDPAC.—The Medicare Payment Advi-*  
20                 *sory Commission shall conduct an independent review*  
21                 *of the alternatives to current tort litigation that are*  
22                 *implemented under grants under subsection (a) to de-*  
23                 *termine the impact of such alternatives on the Medi-*  
24                 *care program under title XVIII of the Social Security*  
25                 *Act, and its beneficiaries.*

1           “(2) *MACPAC.*—*The Medicaid and CHIP Pay-*  
2           *ment and Access Commission shall conduct an inde-*  
3           *pendent review of the alternatives to current tort liti-*  
4           *gation that are implemented under grants under sub-*  
5           *section (a) to determine the impact of such alter-*  
6           *natives on the Medicaid or CHIP programs under ti-*  
7           *ties XIX and XXI of the Social Security Act, and*  
8           *their beneficiaries.*

9           “(3) *REPORTS.*—*Not later than December 31,*  
10           *2016, the Medicare Payment Advisory Commission*  
11           *and the Medicaid and CHIP Payment and Access*  
12           *Commission shall each submit to Congress a report*  
13           *that includes the findings and recommendations of*  
14           *each respective Commission based on independent re-*  
15           *views conducted under paragraphs (1) and (2), in-*  
16           *cluding an analysis of the impact of the alternatives*  
17           *reviewed on the efficiency and effectiveness of the re-*  
18           *spective programs.*

19           “(i) *OPTION TO PROVIDE FOR INITIAL PLANNING*  
20           *GRANTS.*—*Of the funds appropriated pursuant to sub-*  
21           *section (k), the Secretary may use a portion not to exceed*  
22           *\$500,000 per State to provide planning grants to such*  
23           *States for the development of demonstration project applica-*  
24           *tions meeting the criteria described in subsection (c). In se-*  
25           *lecting States to receive such planning grants, the Secretary*

1 *shall give preference to those States in which State law at*  
2 *the time of the application would not prohibit the adoption*  
3 *of an alternative to current tort litigation.*

4 “(j) *DEFINITIONS.—In this section:*

5 “(1) *HEALTH CARE SERVICES.—The term ‘health*  
6 *care services’ means any services provided by a health*  
7 *care provider, or by any individual working under*  
8 *the supervision of a health care provider, that relate*  
9 *to—*

10 “(A) *the diagnosis, prevention, or treatment*  
11 *of any human disease or impairment; or*

12 “(B) *the assessment of the health of human*  
13 *beings.*

14 “(2) *HEALTH CARE ORGANIZATION.—The term*  
15 *‘health care organization’ means any individual or*  
16 *entity which is obligated to provide, pay for, or ad-*  
17 *minister health benefits under any health plan.*

18 “(3) *HEALTH CARE PROVIDER.—The term*  
19 *‘health care provider’ means any individual or enti-*  
20 *ty—*

21 “(A) *licensed, registered, or certified under*  
22 *Federal or State laws or regulations to provide*  
23 *health care services; or*



1 *and apply to any act or omission which occurs on or after*  
2 *that date.*

3 **SEC. 10609. LABELING CHANGES.**

4 *Section 505(j) of the Federal Food, Drug, and Cos-*  
5 *metic Act (21 U.S.C. 355(j)) is amended by adding at the*  
6 *end the following:*

7 *“(10)(A) If the proposed labeling of a drug that is the*  
8 *subject of an application under this subsection differs from*  
9 *the listed drug due to a labeling revision described under*  
10 *clause (i), the drug that is the subject of such application*  
11 *shall, notwithstanding any other provision of this Act, be*  
12 *eligible for approval and shall not be considered misbranded*  
13 *under section 502 if—*

14 *“(i) the application is otherwise eligible for ap-*  
15 *proval under this subsection but for expiration of pat-*  
16 *ent, an exclusivity period, or of a delay in approval*  
17 *described in paragraph (5)(B)(iii), and a revision to*  
18 *the labeling of the listed drug has been approved by*  
19 *the Secretary within 60 days of such expiration;*

20 *“(ii) the labeling revision described under clause*  
21 *(i) does not include a change to the ‘Warnings’ sec-*  
22 *tion of the labeling;*

23 *“(iii) the sponsor of the application under this*  
24 *subsection agrees to submit revised labeling of the*  
25 *drug that is the subject of such application not later*

1       *than 60 days after the notification of any changes to*  
2       *such labeling required by the Secretary; and*

3               *“(iv) such application otherwise meets the appli-*  
4       *cable requirements for approval under this subsection.*

5       *“(B) If, after a labeling revision described in subpara-*  
6       *graph (A)(i), the Secretary determines that the continued*  
7       *presence in interstate commerce of the labeling of the listed*  
8       *drug (as in effect before the revision described in subpara-*  
9       *graph (A)(i)) adversely impacts the safe use of the drug,*  
10       *no application under this subsection shall be eligible for ap-*  
11       *proval with such labeling.”.*

12       ***Subtitle G—Provisions Relating to***  
13               ***Title VIII***

14       ***SEC. 10801. PROVISIONS RELATING TO TITLE VIII.***

15       *(a) Title XXXII of the Public Health Service Act, as*  
16       *added by section 8002(a)(1), is amended—*

17               *(1) in section 3203—*

18                       *(A) in subsection (a)(1), by striking sub-*  
19               *paragraph (E);*

20                       *(B) in subsection (b)(1)(C)(i), by striking*  
21               *“for enrollment” and inserting “for reenroll-*  
22               *ment”; and*

23                       *(C) in subsection (c)(1), by striking “, as*  
24               *part of their automatic enrollment in the*  
25               *CLASS program,”; and*