

106TH CONGRESS  
2D SESSION

# H. R. 5404

To amend title XVIII of the Social Security Act to establish and implement a comprehensive system under the Medicare Program to assure quality of care furnished to medicare beneficiaries, and reduce the incidence of medical errors, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 5, 2000

Mr. STARK (for himself, Mr. NEAL of Massachusetts, Mr. JEFFERSON, and Mr. COYNE) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on 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 establish and implement a comprehensive system under the Medicare Program to assure quality of care furnished to medicare beneficiaries, and reduce the incidence of medical errors, and for other purposes.

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 “Medicare Comprehen-  
5 sive Quality of Care and Safety Act of 2000”.

1 **SEC. 2. ESTABLISHMENT OF MEDICARE COMPREHENSIVE**  
2 **QUALITY OF CARE AND SAFETY SYSTEM.**

3 (a) MEDICARE COMPREHENSIVE QUALITY OF  
4 CARE.—

5 (1) IN GENERAL.—Section 1863 of the Social  
6 Security Act (42 U.S.C. 1395z) is amended to read  
7 as follows:

8 “COMPREHENSIVE QUALITY OF CARE AND SAFETY

9 “SEC. 1863. (a) COMPREHENSIVE QUALITY OF CARE  
10 AND SAFETY SYSTEM.—

11 “(1) ESTABLISHMENT OF SYSTEM.—The Sec-  
12 retary shall establish and maintain a comprehensive  
13 quality of care and safety system for improving and  
14 monitoring the quality of care and safety of medical  
15 care furnished to individuals entitled to benefits  
16 under this title and for reducing medical errors and  
17 protecting the safety of such individuals in their  
18 care. In establishing and maintaining the com-  
19 prehensive quality of care and safety system in this  
20 paragraph, the Secretary shall—

21 “(A) consult with the Medicare Quality  
22 Advisory Committee established in subsection  
23 (h);

24 “(B) perform the functions described in  
25 this section and such other functions as the  
26 Secretary determines appropriate in achieving

1 quality of care and protecting the safety of indi-  
2 viduals entitled to benefits under this title;

3 “(C) coordinate and, to the extent prac-  
4 ticable, ensure consistency between the quality  
5 of care activities in this section and other qual-  
6 ity of care activities under this title and title  
7 XI, including those for Medicare+Choice plans  
8 under part C of this title; and

9 “(D) coordinate all medicare quality of  
10 care activities with other quality of care activi-  
11 ties being conducted within the Department of  
12 Health and Human Services.

13 “(2) CHIEF MEDICARE QUALITY AND SAFETY  
14 OFFICER.—The Secretary shall appoint a Chief  
15 Medicare Quality and Safety Officer to oversee the  
16 comprehensive quality of care and safety system in  
17 this section and other quality of care activities in  
18 this title and title XI.

19 “(b) QUALITY AND SAFETY IMPROVEMENT.—

20 “(1) ESTABLISHMENT OF SYSTEM.—The Sec-  
21 retary shall establish a system to achieve continuous  
22 quality and safety improvement in the delivery of  
23 medical care to individuals entitled to benefits under  
24 this title.

1           “(2) GOALS AND OBJECTIVES.—The Secretary  
2 shall establish goals and specific annual objectives  
3 for achieving continuous quality and safety improve-  
4 ments in the delivery of medical care to individuals  
5 entitled to benefits under this title, including annual  
6 goals and specific objectives for—

7           “(A) types of providers and suppliers of  
8 services;

9           “(B) categories of individuals entitled to  
10 benefits under this title, such as racial, gender,  
11 and socioeconomic categories;

12           “(C) types of services, such as specific pre-  
13 ventive services and other specific services; and

14           “(D) such other categories as the Sec-  
15 retary determines appropriate and beneficial.

16           “(3) COMMON SETS OF MEASUREMENTS.—The  
17 Secretary shall establish common sets of quality and  
18 safety standards, performance measures, and best  
19 practices for each type of provider and supplier and  
20 type of service affecting quality and safety of both  
21 individuals receiving care and employees of providers  
22 and suppliers in providing that care. In establishing  
23 such quality and safety standards, performance  
24 measures, and best practices, the Secretary shall—

1           “(A) collect information concerning quality  
2           and safety standards, performance measures,  
3           and best practices from private sector organiza-  
4           tions and individuals and other governmental  
5           organizations and individuals;

6           “(B) fund research as appropriate to de-  
7           velop knowledge and understanding of quality  
8           of care, patient safety, and medical errors to  
9           gain insight into better system design to im-  
10          prove quality and safety, and to develop quality  
11          and safety standards and performance meas-  
12          ures; and

13          “(C) establish and maintain a national  
14          clearinghouse of quality and safety standards,  
15          performance measures, and best practices.

16          “(c) MONITORING QUALITY OF CARE AND SAFETY.—

17                 “(1) DATA COLLECTION.—The Secretary shall  
18                 establish such data collection systems and collect  
19                 such data as may be necessary on an ongoing basis  
20                 to monitor the quality of care and safety of care pro-  
21                 vided to individuals entitled to benefits under this  
22                 title, and the safety of employees of providers and  
23                 suppliers who provide that care. Such data collection  
24                 systems shall include—

1           “(A) assessments of health and functional  
2 status of individuals receiving care;

3           “(B) measures of appropriate use and out-  
4 comes of care provided;

5           “(C) identification of adverse events, in-  
6 cluding adverse events that result from errors;

7           “(D) performance of providers and sup-  
8 pliers in meeting quality and safety standards  
9 and performance measures;

10           “(E) corrective actions taken by providers  
11 and suppliers when errors and other adverse  
12 events are identified;

13           “(F) satisfaction of individuals receiving  
14 care with the care provided; and

15           “(G) quality standards, performance meas-  
16 ures, and best practices used by providers and  
17 suppliers in achieving improvements in quality  
18 and safety and achieving performance meas-  
19 ures.

20           “(2) ESTABLISHMENT OF COMMON SETS OF  
21 DATA ELEMENTS.—The Secretary shall establish  
22 common sets of data elements and shall ensure com-  
23 parability of data.

24           “(3) COORDINATION OF DATA.—The Secretary  
25 shall coordinate the data systems described in sub-

1 section (e)(1) to form a national database of infor-  
2 mation reported to the quality improvement organi-  
3 zations.

4 “(4) USE OF DATA.—The Secretary shall con-  
5 duct analyses of such data—

6 “(A) to evaluate achievement in meeting  
7 quality and safety standards and performance  
8 standards among various types of providers and  
9 suppliers;

10 “(B) to develop knowledge and under-  
11 standing of medical errors and other adverse  
12 events, to gain insight into better system design  
13 to improve quality and safety, and to develop  
14 quality and safety standards and performance  
15 measures; and

16 “(C) to examine differences in quality of  
17 care, safety, outcomes of care, and satisfaction  
18 with care among different categories of individ-  
19 uals entitled to benefits under this title by gen-  
20 der, race, socioeconomic status, geography, and  
21 type and severity of illness.

22 “(5) PUBLIC ACCESS TO DATA.—The Secretary  
23 shall make such data available for public use in a  
24 form that does not identify individuals, providers or  
25 suppliers, or reporters of information.

1       “(d) STANDARD PATIENT ASSESSMENT INSTRU-  
2       MENTS.—

3               “(1) The Secretary shall establish and imple-  
4       ment standard patient assessment instruments that  
5       provide comparability of information.

6               “(2) CONSULTATION.—In establishing the  
7       standard patient assessment instruments under this  
8       subsection, the Secretary shall consult with rep-  
9       resentatives of providers of services, suppliers, and  
10      with appropriate organizations and entities rep-  
11      resenting private sector entities to promote the de-  
12      velopment and use of common sets of quality meas-  
13      ures that represent the full spectrum of care ob-  
14      tained by individuals entitled to benefits under this  
15      title.

16              “(3) SOLE ASSESSMENT INSTRUMENTS.—The  
17      standard patient assessment instruments established  
18      under this subsection shall be the sole patient as-  
19      sessment instrument utilized by the Secretary with  
20      respect to items and services furnished under this  
21      title, and shall supersede any patient assessment in-  
22      strument or method utilized by the Secretary with  
23      respect to such items and services.

24              “(4) ADJUSTMENT TO PAYMENT AMOUNTS FOR  
25      SERVICES.—Notwithstanding any other provision of

1 law, the Secretary shall use the standard patient as-  
2 sessment instruments established under this sub-  
3 section in determining payments amounts under this  
4 title for items and services.

5 “(e) REQUIREMENTS FOR QUALITY IMPROVEMENT  
6 ORGANIZATIONS.—The Secretary shall enter into agree-  
7 ments with quality improvement organizations to carry out  
8 the following functions:

9 “(1) IMPLEMENTATION OF DATA COLLECTION  
10 SYSTEM.—To implement a standard data collection  
11 system established by the Secretary to collect—

12 “(A) mandatory reports from providers  
13 and suppliers on serious preventable adverse  
14 events (as determined by the Secretary in regu-  
15 lations);

16 “(B) voluntary reports of near misses (as  
17 determined by the Secretary in regulations),  
18 clinical systems problems, or other failures to  
19 meet quality or safety standards or performance  
20 standards;

21 “(C) reports of investigations of root  
22 causes of serious preventable adverse events  
23 and near misses;

24 “(D) corrective actions taken to address  
25 identified quality and safety problems;

1           “(E) data and information obtained in con-  
2           ducting sampling of medical records and other  
3           investigations of medical care;

4           “(F) data on performance of providers and  
5           suppliers in achieving quality standards and  
6           performance measures; and

7           “(G) such other information as the Sec-  
8           retary determines appropriate.

9           “(2) REMOVAL FROM DATA OF PERSONALLY  
10          IDENTIFIABLE INFORMATION.—To modify the data  
11          received to remove identification of patients, pro-  
12          viders or suppliers, and reporters of the information,  
13          and to enter the information into a database.

14          “(3) INVESTIGATIONS OF ADVERSE EVENTS.—  
15          To investigate serious preventable adverse events at  
16          providers and suppliers as reported through the  
17          mandatory reporting system.

18          “(4) ASSISTANCE WITH CORRECTIVE ACTION  
19          PLANS.—To assist providers and suppliers to imple-  
20          ment appropriate corrective action plans in response  
21          to identification of serious preventable adverse  
22          events.

23          “(5) DISSEMINATION OF INFORMATION TO PRO-  
24          VIDERS.—To provide dissemination of information  
25          and ongoing training to providers and suppliers re-

1        regarding quality and safety standards, performance  
2        measures, best practices, analyses of information re-  
3        garding quality or safety, and other quality and  
4        safety improvement information.

5            “(6) FORUMS FOR DISCUSSIONS OF BEST PRAC-  
6        TICES AND MEDICAL ERRORS.—To provide a means  
7        of convening of providers and suppliers to discuss  
8        medical errors, failures to achieve quality or safety  
9        standards, performance measures, best practices,  
10       lessons learned by other providers and suppliers, and  
11       other quality and safety issues.

12           “(7) REVIEW OF MEDICAL RECORDS.—To con-  
13       duct ongoing sampling and clinical data abstraction  
14       of medical records of providers and suppliers and  
15       data submitted by providers and suppliers on patient  
16       assessment instruments to identify quality and safe-  
17       ty problems and opportunities for improvement.

18           “(8) ANALYSIS OF DATA.—To conduct analyses  
19       of the data included in the database to identify  
20       issues indicating quality or safety problems, needed  
21       systems changes, and opportunities for improvement.

22           “(9) FEEDBACK TO PROVIDERS.—To provide  
23       ongoing feedback to providers, suppliers, and other  
24       individuals regarding reports, lessons learned from  
25       reports, investigations, and corrective actions.

1           “(10) PROTECTING PERSONALLY IDENTIFIABLE  
2 INFORMATION.—The provisions of section 1160 (re-  
3 lating to prohibition against disclosure of informa-  
4 tion) apply with respect to data or information on  
5 adverse events reported to quality improvement or-  
6 ganizations under this section, including such infor-  
7 mation disseminated or discussed as provided for  
8 under this subsection, in the same manner as such  
9 provisions apply to information data or information  
10 acquired by such an organization in the exercise of  
11 its duties and functions under section 1160.

12           “(11) MAINTENANCE OF A TOLL-FREE TELE-  
13 PHONE NUMBER.—To provide information via a toll-  
14 free telephone number.

15           “(f) REQUIREMENTS FOR PROVIDERS AND SUP-  
16 PLIERS.—Providers and suppliers furnishing items and  
17 services under this title shall establish and maintain a  
18 Medicare Quality and Safety Program, which shall include  
19 the following elements:

20           “(1) CHIEF MEDICAL QUALITY AND SAFETY OF-  
21 FICER.—Designation of a senior level Chief Medical  
22 Quality and Safety Officer.

23           “(2) WRITTEN STANDARDS OF QUALITY  
24 CARE.—Written standards for quality of care and  
25 patient and employee safety, including error preven-

1 tion, consistent with those promulgated by the Sec-  
2 retary under subsection (b)(2), and policies and pro-  
3 cedures for implementing those standards, including  
4 disciplinary standards.

5 “(3) WRITTEN STANDARDS FOR PATIENTS  
6 CARE.—Written standards for patient assessment,  
7 preparation of a plan of care for each patient (in-  
8 cluding participation of the patient in clinical deci-  
9 sion making), coordination of services among all  
10 those providing services for the patient, monitoring  
11 of quality, safety, and patient improvement, and  
12 records management.

13 “(4) ONGOING EDUCATION AND TRAINING.—  
14 Ongoing conduct of effective education and training  
15 of employees regarding quality and safety, including  
16 the prevention of errors.

17 “(5) ONGOING MONITORING AND REPORTING.—  
18 Ongoing monitoring and internal reporting of med-  
19 ical quality and safety, including monitoring and re-  
20 porting of serious preventable adverse events.

21 “(6) PROMPT DISCUSSION OF ADVERSE  
22 EVENTS.—Prompt discussion with patients of ad-  
23 verse events, including adverse events that result  
24 from errors, and providing access to the patients of  
25 information relating to such events.

1           “(7) PROMPT REPORTING OF MEDICAL ER-  
2           RORS.—Prompt reporting (as determined by the  
3           Secretary) to the quality improvement organizations  
4           of serious preventable adverse events, including ad-  
5           verse events that result from errors, using standard  
6           formats promulgated by the Secretary, and including  
7           encouragement of reporting by employees.

8           “(8) COOPERATION IN CASE OF INVESTIGA-  
9           TIONS.—Cooperation with the quality improvement  
10          organizations in investigating causes of serious pre-  
11          ventable adverse events, including adverse events  
12          that result from errors, near misses, or other inves-  
13          tigations of quality or safety.

14          “(9) COOPERATION IN DEVELOPMENT OF COR-  
15          RECTIVE ACTION PLANS.—Cooperation with the  
16          quality improvement organizations in developing cor-  
17          rective action plans to address a serious preventable  
18          adverse event, including an adverse event that re-  
19          sults from an error, or a corrective action plan to  
20          address other quality or safety problems.

21          “(10) COOPERATION IN PREPARING ANNUAL  
22          REPORTS.—Cooperation with the quality improve-  
23          ment organizations in preparing public annual re-  
24          ports on progress in meeting quality and safety

1 standards and performance measures, as determined  
2 by the Secretary.

3 Notwithstanding any other provision of law, a provider or  
4 supplier may report adverse events, including those result-  
5 ing from errors, as provided under this section without  
6 the consent of the individual who was furnished the med-  
7 ical care which gave rise to the adverse event.

8 “(g) WHISTLEBLOWER PROTECTIONS.—A provider  
9 of services or supplier may not penalize or take adverse  
10 action against an employee because the employee reports  
11 an adverse event to a quality improvement organization,  
12 or submits data or information to the Secretary with re-  
13 spect to the quality of items or services furnished under  
14 this title by such provider or supplier, consistent with the  
15 requirements of this section.

16 “(h) MEDICARE QUALITY AND SAFETY ADVISORY  
17 COMMITTEE.—

18 “(1) ESTABLISHMENT.—The Secretary shall es-  
19 tablish the Medicare Quality Advisory Committee  
20 (hereinafter in this subsection referred to as the  
21 ‘Committee’). The Secretary shall consult with the  
22 Committee, and may consult directly with any panel  
23 that the Committee establishes.

1           “(2) DUTIES.—The Committee, and its panels,  
2 shall provide advice and recommendations to the  
3 Secretary with respect to—

4           “(A) the quality and safety of medical care  
5 furnished to individuals entitled to benefits  
6 under this title, including such individuals en-  
7 rolled in Medicare+Choice plans under part C  
8 of this title;

9           “(B) establishment of goals and specific  
10 annual objectives with respect to such quality  
11 and safety; and

12           “(C) other issues relating to such quality  
13 and safety, including—

14           “(i) reporting and collection of data,

15           “(ii) appropriate research and anal-  
16 ysis of data,

17           “(iii) quality and safety standards,  
18 performance measures, and best practices,

19           “(iv) dissemination of information to  
20 beneficiaries on treatment options,

21           “(v) dissemination of information on  
22 quality of care and safety to providers and  
23 suppliers, and

24           “(vi) such other quality of care and  
25 safety issues as the Committee may con-

1           sider appropriate, or of which as the Sec-  
2           retary requests recommendations.

3           “(3) MEMBERSHIP; TERMS; COMPENSATION.—

4           “(A) MEMBERSHIP.—

5           “(i) NUMBER AND APPOINTMENT.—

6           The Commission shall be composed of 17  
7           members, of whom 14 shall be appointed  
8           in accordance with clause (ii) and 3 ap-  
9           pointed in accordance with in clause (iii).

10          “(ii) PRIVATE INDIVIDUALS.—

11          “(I) IN GENERAL.—The Sec-  
12          retary shall appoint 14 members from  
13          among individuals who are qualified  
14          by training and experience to evaluate  
15          the matters referred to the Committee  
16          and who are not officers or employees  
17          of the United States.

18          “(II) PROVISIONS FOR CONFLICT  
19          OF INTEREST.—Members shall recuse  
20          themselves from participation in mat-  
21          ters which present a potential per-  
22          sonal conflict of interest or appear-  
23          ance of such conflict that might intro-  
24          duce bias in the process of making

1 recommendations under this sub-  
2 section.

3 “(iii) INDIVIDUALS REPRESENTING  
4 ORGANIZATIONS.—The Secretary shall ap-  
5 point one member from each of the fol-  
6 lowing organizations:

7 “(I) The Medicare Coverage Ad-  
8 visory Committee.

9 “(II) A quality improvement or-  
10 ganization.

11 “(III) The National Advisory  
12 Council for Healthcare Research and  
13 Quality.

14 “(B) TERMS.—

15 “(i) IN GENERAL.—Members of the  
16 Committee appointed under subparagraph  
17 (A) shall serve for a term of 3 years.

18 “(ii) STAGGERED TERMS.—To ensure  
19 the staggered rotation of one-third of the  
20 members of the Committee each year, the  
21 Secretary is authorized to appoint the ini-  
22 tial members of the Committee for terms  
23 of 1, 2, or 3 years.

24 “(iii) SERVICE BEYOND TERM.—A  
25 member of the Committee appointed under

1           subparagraph (A) may continue to serve  
2           after the expiration of the term of the  
3           members until a successor is appointed.

4           “(iv) VACANCIES.—If a member of  
5           the Advisory Council appointed under sub-  
6           paragraph (A) does not serve the full term  
7           applicable under this subparagraph, the in-  
8           dividual appointed to fill the resulting va-  
9           cancy shall be appointed for the remainder  
10          of the term of the predecessor of the indi-  
11          vidual.

12          “(v) CHAIR.—The Secretary shall,  
13          from among the members of the Com-  
14          mittee appointed under subparagraph  
15          (A)(ii), designate an individual to serve as  
16          the chair of the Committee.

17          “(C) COMPENSATION.—

18          “(i) PRIVATE INDIVIDUALS.—Mem-  
19          bers of the Committee appointed under  
20          subparagraph (A)(ii) shall receive com-  
21          pensation for each day (including travel  
22          time) engaged in carrying out the duties of  
23          the Advisory Council unless declined by the  
24          member. Such compensation may not be in  
25          an amount in excess of the daily equivalent

1 of the annual rate of basic pay prescribed  
2 for level IV of the Executive Schedule  
3 under section 5315 of title 5, United  
4 States Code, for each day during which  
5 such member is engaged in the perform-  
6 ance of the duties of the Advisory Council.

7 “(ii) INDIVIDUALS REPRESENTING OR-  
8 GANIZATIONS.—Members appointed under  
9 subparagraph (A)(iii) may not receive com-  
10 pensation for service on the Committee in  
11 addition to the compensation otherwise re-  
12 ceived for duties carried out as members of  
13 the organization.

14 “(4) REPORT.—

15 “(A) ANNUAL REPORT TO THE SEC-  
16 RETARY.—Not later than May 1 of every year  
17 beginning with 2002, the Committee shall sub-  
18 mit to the Secretary a report on—

19 “(i) the activities of the Committee  
20 during the preceding year;

21 “(ii) progress by providers of services  
22 and suppliers in meeting goals and objec-  
23 tives for improvement of the quality of  
24 items and services furnished under this  
25 title during such fiscal year; and

1                   “(iii) any recommendation of the  
2                   Committee with respect to quality of care  
3                   issues under this title.

4                   “(B) PUBLICATION OF REPORT.—Not later  
5                   than 60 days after receipt of the report under  
6                   subparagraph (A), the Secretary shall publish  
7                   the report, together with any supplemental  
8                   views of the Secretary, on the Internet site of  
9                   the Department of Health and Human Services.

10                  “(5) DURATION.—Section 14(a)(2)(B) of the  
11                  Federal Advisory Committee Act (5 U.S.C. App.; re-  
12                  lating to the termination of advisory committees)  
13                  shall not apply to the Committee.

14                  “(i) REPORT TO CONGRESS.—The Secretary shall  
15                  submit to Congress an annual report on the progress of  
16                  providers and suppliers in meeting the goals and objectives  
17                  for improving quality of medical care and safety for indi-  
18                  viduals entitled to benefits under this title.

19                  “(j) DEFINITIONS.—In this section:

20                         “(1) ADVERSE EVENT.—The term ‘adverse  
21                         event’ means an unintended effect of medical inter-  
22                         vention that results in harm to a patient.

23                         “(2) PREVENTABLE ADVERSE EVENT.—The  
24                         term ‘preventable adverse event’ means an adverse

1 event that is preventable, including those that result  
2 from errors.”.

3 (2) EFFECTIVE DATE.—The amendment made  
4 by paragraph (1) shall apply to items and services  
5 furnished on or after—

6 (A) in the case of a hospital, rehabilitation  
7 unit, or end stage renal disease provider, Octo-  
8 ber 1, 2001; and

9 (B) in the case of any other provider or  
10 supplier, at such time as the Secretary deter-  
11 mines appropriate, but in no event earlier than  
12 October 1, 2001.

13 (3) CONFORMING AMENDMENTS.—

14 (A) CONSULTATION WITH STATE AGEN-  
15 CIES.—(i) Section 1864 of the Social Security  
16 Act (42 U.S.C. 1395aa) is amended by adding  
17 at the end the following new subsection:

18 “(f) In carrying out functions, relating to determina-  
19 tion of conditions of participation by providers of services,  
20 under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I),  
21 and (dd)(2) of section 1861, or by ambulatory surgical  
22 centers under section 1832(a)(2)(F)(i), the Secretary shall  
23 consult with appropriate State agencies and recognized  
24 national listing or accrediting bodies, and may consult  
25 with appropriate local agencies. Such conditions pre-

1 scribed under any of such subsections may be varied for  
2 different areas or different classes of institutions or agen-  
3 cies and may, at the request of a State, provide higher  
4 requirements for such State than for other States; except  
5 that, in the case of any State or political subdivision of  
6 a State which imposes higher requirements on institutions  
7 as a condition to the purchase of services (or of certain  
8 specified services) in such institutions under a State plan  
9 approved under title I, XVI, or XIX, the Secretary shall  
10 impose like requirements as a condition to the payment  
11 for services (or for the services specified by the State or  
12 subdivision) in such institutions in such State or subdivi-  
13 sion.”.

14 (ii) The heading to such section is amended by  
15 adding at the end the following:

16 “CONSULTATION WITH STATE AGENCIES AND OTHER OR-  
17 GANIZATIONS TO DEVELOP CONDITIONS OF PARTICI-  
18 PATION FOR PROVIDERS OF SERVICES”.

19 (B) CHIEF MEDICARE QUALITY AND SAFE-  
20 TY OFFICER.—Section 1117 of the Social Secu-  
21 rity Act (42 U.S.C. 1317) is amended—

22 (i) in the heading, by striking “AND  
23 CHIEF ACTUARY” and inserting “, CHIEF  
24 ACTUARY, AND CHIEF MEDICARE QUALITY  
25 AND SAFETY OFFICER”; and

1 (ii) by adding at the end the fol-  
2 lowing:

3 “(c)(1) There is established in the Health Care Fi-  
4 nancing Administration the position of Chief Medicare  
5 Quality and Safety Officer. The Chief Medicare Quality  
6 and Safety Officer shall be appointed by, and in direct  
7 line of authority to, the Administrator of such Administra-  
8 tion. The Chief Medicare Quality and Safety Officer shall  
9 be appointed from among individuals who have dem-  
10 onstrated, by their education and experience, superior ex-  
11 pertise in the quality in the delivery of health care services.  
12 The Chief Medicare Quality and Safety Officer shall exer-  
13 cise such duties as are appropriate for the office of the  
14 Chief Medicare Quality and Safety Officer. The Chief  
15 Medicare Quality and Safety Officer may be removed only  
16 for cause.

17 “(2) The Chief Medicare Quality and Safety Officer  
18 shall be compensated at the highest rate of basic pay for  
19 the Senior Executive Service under section 5382(b) of title  
20 5, United States Code.”.

21 (b) AGREEMENTS WITH PROVIDERS AND SUP-  
22 PLIERS.—

23 (1) IN GENERAL.—Section 1866(a)(1) of the  
24 Social Security Act (42 U.S.C. 1395cc(a)(1)) is  
25 amended—

1 (A) at the end of subparagraph (R) by  
2 striking “and”;

3 (B) at the end of subparagraph (S) by  
4 striking the period and inserting “, and”; and

5 (C) by inserting after subparagraph (S)  
6 the following new subparagraph:

7 “(T) to carry out requirements with respect to  
8 comprehensive quality of medical care and safety for  
9 items and services furnished to individuals entitled  
10 to benefits under this title imposed under section  
11 1863, in such manner and within such timeframes  
12 as the Secretary establishes in regulations, including  
13 prompt reporting of medical errors to the Secretary  
14 or to quality improvement organizations.”.

15 (2) EFFECTIVE DATE.—The amendments made  
16 by paragraph (1) shall apply to items and services  
17 furnished on or after—

18 (A) in the case of a hospital, rehabilitation  
19 unit, or end stage renal disease provider, Octo-  
20 ber 1, 2001; and

21 (B) in the case of any other provider or  
22 supplier, at such time as the Secretary deter-  
23 mines appropriate, but in no event earlier than  
24 October 1, 2001.

1 (c) REDESIGNATION OF PEER REVIEW ORGANIZA-  
 2 TION AS QUALITY IMPROVEMENT ORGANIZATION.—

3 (1) UTILIZATION AND QUALITY CONTROL PEER  
 4 REVIEW ORGANIZATION.—

5 (A) IN GENERAL.—The following sections  
 6 of the Social Security Act are each amended by  
 7 striking “utilization and quality control peer re-  
 8 view organization” each place it appears and in-  
 9 serting “quality improvement organization”:

10 (i) TITLE XI.—1128A(h), 1151,  
 11 1153(b)(1), the second sentence of  
 12 1153(c), 1153(d)(3), 1153(d)(4), 1154(a),  
 13 1154(c), 1154(d), 1156(c), 1158(a), and  
 14 1161(a)(1) (42 U.S.C. 1320a-7a(h),  
 15 1320c, 1320c-2(b)(1), 1320c-2(c), 1320c-  
 16 2(d)(3), 1320c-2(d)(4), 1320c-3(a),  
 17 1320c-3(c), 1320c-3(d), 1320c-5(c),  
 18 1320c-7(a), 1320c-10(a)(1), respectively).

19 (ii) TITLE XVIII.—1862(a)(15)(A),  
 20 1862(g), 1866(a)(1)(F)(i),  
 21 1866(a)(1)(F)(ii), 1867(d)(3),  
 22 1876(i)(7)(A), 1879(a), and 1886(f)(2)  
 23 (42 U.S.C. 1395y(a)(15)(A), 1395y(g),  
 24 1395cc(a)(1)(F)(i), 1395cc(a)(1)(F)(ii),  
 25 1395dd(d)(3), 1395mm(i)(7)(A),

1                   1395pp(a), and 1395ww(f)(2) respec-  
2                   tively).

3                   (iii)           TITLE           XIX.—1902(d),  
4                   1903(a)(3)(C)(i), and section 1921(b)(4)  
5                   (42 U.S.C. 1396a(d), 1396b(a)(3)(C)(i),  
6                   and 1396r-2(b)(4), respectively).

7                   (B) HEADINGS.—The headings of the fol-  
8                   lowing sections of title XI of the Social Security  
9                   Act are each amended by striking “UTILIZA-  
10                  TION AND QUALITY CONTROL PEER REVIEW OR-  
11                  GANIZATION” each place it appears and insert-  
12                  ing “QUALITY IMPROVEMENT ORGANIZATION”:  
13                  1152, 1153, and 1163 (42 U.S.C. 1320c-1,  
14                  1320c-2, and 1320c-12, respectively).

15                  (2) PEER REVIEW ORGANIZATION.—The fol-  
16                  lowing sections of the Social Security Act are each  
17                  amended by striking “peer review organization” each  
18                  place it appears and inserting “quality improvement  
19                  organization”:

20                  (A) TITLE XI.—1153(e)(2), 1153(h)(3),  
21                  1154(a)(2)(B),                           1154(a)(3)(E)(i),  
22                  1154(a)(4)(A), 1154(a)(4)(C), 1154(e)(2),  
23                  1154(e)(3)(A)(ii),                           1154(e)(3)(B),  
24                  1154(e)(4)(B), 1155, 1156(a)(3), and  
25                  1160(b)(1) (42 U.S.C. 1320c-2(e)(2), 1320c-

1           2(h)(3),           1320c-3(a)(2)(B),           1320c-  
 2           3(a)(3)(E)(i),       1320c-3(a)(4)(A),       1320c-  
 3           3(a)(4)(C),           1320c-3(e)(2),           1320c-  
 4           3(e)(3)(A)(ii),       1320c-3(e)(3)(B),       1320c-  
 5           3(e)(4)(B),   1320c-4,   1320c-5(a)(3),   and  
 6           1320c-9(b)(1), respectively).

7           (B)   TITLE   XVIII.—1820(c)(2)(B)(iii),  
 8           1820(d)(2)(C)(ii),           1842(l)(1)(A)(iii)(I),  
 9           1842(l)(2), and 1866(a)(3) (42 U.S.C. 1395i-  
 10          4(e)(2)(B)(iii),           1395i-4(d)(2)(C)(ii),  
 11          1395u(l)(1)(A)(iii)(I),   1395u(l)(2),   and  
 12          1395cc(a)(3), respectively).

13          (C)   TITLE   XIX.—1921(a)(1) (42 U.S.C.  
 14          1396r-2(a)(1)).

15          (3) PEER REVIEW ORGANIZATIONS.—

16               (A)   IN   GENERAL.—Sections   1151,  
 17               1153(g), 1154(a)(10)(B), and 1154(f) of the  
 18               Social Security Act (42 U.S.C. 1320c, 1320c-  
 19               2(g), and 1320c-3(a)(10)(B), respectively) are  
 20               each amended by striking “peer review organi-  
 21               zations” each place it appears and inserting  
 22               “quality improvement organizations”.

23               (B)   HEADINGS.—The headings of sections  
 24               1154 and 1867(d)(3) of the Social Security Act  
 25               (42 U.S.C. 1320c-3 and 1395dd, respectively)

1 are each amended by striking “PEER REVIEW  
2 ORGANIZATIONS” and inserting “QUALITY IM-  
3 PROVEMENT ORGANIZATIONS”.

4 (4) QUALITY CONTROL AND PEER REVIEW OR-  
5 GANIZATION.—The following sections of title XVIII  
6 of the Social Security Act are each amended by  
7 striking “quality control and peer review organiza-  
8 tion” each place it appears and inserting “quality  
9 improvement organization”: 1815(b),  
10 1832(a)(2)(F)(ii)(I), 1861(v)(1)(G)(i), 1861(w)(2),  
11 and 1879(e) (42 U.S.C. 1395g(b),  
12 1395k(a)(2)(F)(ii)(I), 1395x(v)(1)(G)(i),  
13 1395x(w)(2), and 1395pp, respectively).

14 (5) REFERENCES.—Any reference in a law, reg-  
15 ulation, document, paper, or other record of the  
16 United States to a “peer review organization”, “uti-  
17 lization and quality control peer review organiza-  
18 tion”, or “quality control and peer review organiza-  
19 tion” under part B of title XI of the Social Security  
20 Act shall be deemed to be a reference to a “quality  
21 improvement organization” under such part.

22 (d) ADDITIONAL PROVISIONS REGARDING QUALITY  
23 IMPROVEMENT ORGANIZATIONS.—

24 (1) EXPANSION OF QUALITY REVIEW AUTHOR-  
25 ITY TO ALL PROVIDERS AND SUPPLIERS.—

1           (A) IN GENERAL.—Section 1154 of the So-  
2           cial Security Act (42 U.S.C. 1320c-3) is  
3           amended by adding at the end the following  
4           new subsection:

5           “(g) In this section, the terms ‘providers of health  
6           care services’ and ‘provider’ includes suppliers of items  
7           under title XVIII and Medicare+Choice organizations of-  
8           fering Medicare+Choice plans under part C of such title.

9           (B) EXPANSION OF CATEGORY OF SERV-  
10           ICES FOR WHICH REVIEW MAY BE RE-  
11           QUESTED.—Section 1154(e) of the Social Secu-  
12           rity Act (42 U.S.C. 1320c-3(e)) is amended—

13           (i) in paragraph (1)(A)—

14                   (I) by striking “hospital” and in-  
15                   serting “provider”; and

16                   (II) by striking “inpatient hos-  
17                   pital care” and inserting “items or  
18                   services furnished”;

19           (ii) in paragraph (1)(B) by striking  
20           “hospital’s” and inserting “provider’s”;

21           (iii) in the matter following subpara-  
22           graph (B) of paragraph (1), by striking  
23           “hospital” and inserting “provider”;

24           (iv) in paragraph (2)(A)—

1 (I) by striking “hospital” and in-  
2 sserting “provider”; and

3 (II) by striking “inpatient hos-  
4 pital care” and inserting “items or  
5 services furnished”;

6 (v) in paragraph (2)(B) by striking  
7 “hospital’s” and inserting “provider’s”;

8 (vi) in the matter following subpara-  
9 graph (B) of paragraph (2)—

10 (I) by striking “hospital” each  
11 place it appears and inserting “pro-  
12 vider”; and

13 (II) by striking “hospital’s” and  
14 inserting “provider’s”;

15 (vii) in paragraph (3)(A), in the mat-  
16 ter following clause (ii) of such  
17 paragraph—

18 (I) by striking “hospital’s” and  
19 inserting “provider’s”;

20 (II) by striking “the hospital”  
21 each place it appears and inserting  
22 “the provider”; and

23 (III) by striking “continued hos-  
24 pital care” and inserting “continued  
25 care”;

1 (viii) in paragraph (3)(B)—

2 (I) in the matter preceding clause  
3 (i), by striking “an inpatient in the  
4 hospital” and inserting “a patient  
5 being furnished items or services by  
6 the provider”; and

7 (II) in clause (i), by striking  
8 “hospital” and inserting “provider”;  
9 and

10 (ix) in paragraph (4)—

11 (I) by striking “the hospital” and  
12 inserting “the provider”; and

13 (II) by striking “inpatient hos-  
14 pital services” and inserting “items or  
15 services”.

16 (C) CONDITION OF PARTICIPATION FOR  
17 ALL PROVIDERS, SUPPLIERS, AND  
18 MEDICARE+CHOICE ORGANIZATIONS.—Section  
19 1886(a) of the Social Security Act (42 U.S.C.  
20 1395ww(a)) is amended—

21 (i) in paragraph (1)(F)(ii), by striking  
22 “and home health agencies,” and “or agen-  
23 cy” and inserting “home health agencies,  
24 other provider of services, suppliers, and  
25 Medicare+Choice organizations offering

1 Medicare+Choice plans under part ” and  
2 “agency, other provider of services, sup-  
3 plier, or Medicare+Choice organization”,  
4 respectively; and

5 (ii) in paragraph (3), by striking “or  
6 agency” each place it appears and insert-  
7 ing “agency, other provider of services,  
8 supplier, or Medicare+Choice organiza-  
9 tion”.

10 (D) CONDUCT OF PROVIDER AND SUP-  
11 PLIER PROFILING.—Section 1154(a) of the So-  
12 cial Security Act (42 U.S.C. 1320c–3(a)) is  
13 amended by adding at the end the following  
14 new paragraph:

15 “(17) The organization shall monitor and pro-  
16 file billing patterns of providers of services within  
17 each area or locality and provide comparative data  
18 to providers of services whose utilization patterns  
19 vary significantly from other providers of services in  
20 the same payment area or locality.”.

21 (2) PROHIBITION ON CONDUCT OF FRAUD AND  
22 ABUSE INVESTIGATIONS.—Section 1154(a) of the  
23 Social Security Act (42 U.S.C. 1320c–3(a)) is  
24 amended by inserting after paragraph (11) the fol-  
25 lowing new paragraph:

1           “(12) The organization shall not conduct activi-  
2 ties that the Secretary, acting through the Office of  
3 the Inspector General of the Department of Health  
4 and Human Services, and the Attorney General con-  
5 duct under sections 1128C, 1128D, or 1128E with  
6 respective to the program to control fraud and abuse  
7 established and carried out under those sections and  
8 under the Medicare Integrity Program under section  
9 1893.”.

10           (3) AUTHORIZING THE SECRETARY TO APPROVE  
11 CONTRACT OBJECTIVES.—(A) Section 1153(c)(7) of  
12 the Social Security Act (42 U.S.C. 1320c–2(c)(7)) is  
13 amended—

14           (i) by striking “shall” and inserting  
15 “may”; and

16           (ii) by striking “negotiated” each place it  
17 appears.

18           (B) Section 1154(a)(4)(A) of such Act (42  
19 U.S.C. 1320c–3(a)(4)(A)) is amended by striking  
20 “after consultation with the Secretary” and insert-  
21 ing “upon approval of the Secretary”.

22           (4) CLARIFYING THE AUTHORITY OF THE SEC-  
23 RETARY TO REQUIRE ORGANIZATIONS TO CONSIDER  
24 CERTAIN CRITERIA AND CASES.—Section  
25 1154(a)(4)(A) of the Social Security Act (42 U.S.C.

1 1320c-3(a)(4)(A)), as amended by paragraph  
2 (3)(B), is further amended by inserting after the  
3 first sentence the following: “IN carrying out the  
4 previous sentence, the organization shall consider  
5 types and kinds of cases and shall apply such guide-  
6 lines as the Secretary determines appropriate, in-  
7 cluding national, professionally-developed standards  
8 of care.”.

9 (5) ELIMINATION OF REQUIREMENT FOR MAN-  
10 DATORY PRIOR APPROVAL FOR USE OF ASSISTANT  
11 AT CATARACT SURGERY.—Section 1862(a)(15) of  
12 the Social Security Act (42 U.S.C. 1395y(a)(15)) is  
13 amended by striking “(A) which are for” and all  
14 that follows through “(B) which are for” and insert-  
15 ing “which are for”.

16 (6) ELIMINATION OF ON SITE REVIEW RE-  
17 QUIREMENT.—Section 1154(a) of the Social Security  
18 Act (42 U.S.C. 1320c-3(a)) is amended by striking  
19 paragraph (15).

20 (7) CLARIFYING THE AUTHORITY OF THE SEC-  
21 RETARY TO DECLINE TO RENEW A CONTRACT WITH  
22 AN ORGANIZATION FOR REASONS OTHER THAN POOR  
23 PERFORMANCE.—Section 1153(c)(4) of the Social  
24 Security Act (42 U.S.C. 1320c-2(c)(4)) is amended  
25 by inserting “on the basis of the organization’s per-

1 performance or of any other criteria the Secretary de-  
2 termines appropriate” after “if the Secretary intends  
3 not to renew a contract”.

4 (8) ELIMINATION OF DUPLICATIVE REPORTING  
5 REQUIREMENT.—Title XI of the Social Security Act  
6 (42 U.S.C. 1301 et seq.) is amended by striking sec-  
7 tion 1161.

8 (9) EFFECTIVE DATE.—The amendments made  
9 by this subsection take effect the date of the enact-  
10 ment of this Act and apply to contracts entered into  
11 or renewed on or after that date.

○