

106TH CONGRESS  
2D SESSION

# S. 2378

To amend titles XVIII and XIX of the Social Security Act to improve the safety of the medicare and medicaid programs, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

APRIL 6, 2000

Mr. GRASSLEY (for himself, Mr. LIEBERMAN, Mr. KERREY, and Mr. BRYAN) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend titles XVIII and XIX of the Social Security Act to improve the safety of the medicare and medicaid programs, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Stop All Frequent Errors (SAFE) in Medicare and Med-  
6 icaid Act of 2000”.

7 (b) TABLE OF CONTENTS.—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Purposes.

Sec. 3. Improvement of patient safety under the medicare program.

“PART D—ADDITIONAL RESPONSIBILITIES FOR THE SECRETARY IN ORDER  
TO IMPROVE HEALTH CARE QUALITY

“Sec. 1860A. Definitions.

“Sec. 1860B. Establishment of patient safety programs.

“Sec. 1860C. Patient safety reporting system.

“Sec. 1860D. Confidentiality and privacy protections.

Sec. 4. Improvement of patient safety under the medicaid program.

Sec. 5. Establishment of the Center for Patient Safety.

Sec. 6. Grants to establish patient safety programs.

1 **SEC. 2. PURPOSES.**

2 The purposes of this Act are as follows:

3 (1) To develop a nonpunitive error reduction  
4 system under the medicare and medicaid programs  
5 under titles XVIII and XIX of the Social Security  
6 Act (42 U.S.C. 1395 et seq.; 1396 et seq.) with  
7 pragmatic reporting requirements and adequate legal  
8 protections to support the collection of information  
9 under such systems.

10 (2) To extend existing confidentiality and peer  
11 review protections to the additional required reports  
12 of error under such systems that are developed for  
13 safety and quality improvement purposes under the  
14 medicare and medicaid programs.

15 (3) To create leadership, research, tools, and  
16 protocols to enhance the knowledge base concerning  
17 patient safety under the medicare and medicaid pro-  
18 grams.

1           (4) To raise standards and expectations for im-  
 2           provements in patient safety under the medicare and  
 3           medicaid programs.

4           (5) To reduce deaths, serious injuries, and  
 5           other health care errors under the medicare and  
 6           medicaid programs through the implementation of  
 7           safe practices at the delivery level.

8   **SEC. 3. IMPROVEMENT OF PATIENT SAFETY UNDER THE**  
 9                           **MEDICARE PROGRAM.**

10       (a) IN GENERAL.—Title XVIII of the Social Security  
 11   Act (42 U.S.C. 1395 et seq.) is amended by redesignating  
 12   part D as part E and by inserting after part C the fol-  
 13   lowing new part:

14   “PART D—ADDITIONAL RESPONSIBILITIES FOR THE  
 15       SECRETARY IN ORDER TO IMPROVE HEALTH CARE  
 16       QUALITY

17                           “DEFINITIONS

18       “SEC. 1860A. In this part:

19           “(1) ADDITIONAL ERROR EVENT.—The term  
 20       ‘additional error event’ means an event other than a  
 21       sentinel event that the Secretary, in consultation  
 22       with the Agency for Healthcare Research and Qual-  
 23       ity, national accrediting organizations, provider and  
 24       consumer organizations, and peer review organiza-  
 25       tions, determines is a health care error, such as a

1 medication error, that has been demonstrated to  
 2 contribute substantially to morbidity and mortality.

3 “(2) APPLICABLE EVENT.—The term ‘applica-  
 4 ble event’ means—

5 “(A) a sentinel event; and

6 “(B) an additional error event.

7 “(3) MEDICAID PROGRAM.—The term ‘medicaid  
 8 program’ means the health care program under title  
 9 XIX.

10 “(4) MEDICARE PROGRAM.—The term ‘medi-  
 11 care program’ means the health care program under  
 12 this title.

13 “(5) PROVIDER OF SERVICES.—The term ‘pro-  
 14 vider of services’ means a hospital, critical access  
 15 hospital, skilled nursing facility, comprehensive out-  
 16 patient rehabilitation facility, home health agency,  
 17 renal dialysis facility, ambulatory surgical center, or  
 18 hospice program.

19 “(6) SENTINEL EVENT.—

20 “(A) IN GENERAL.—The term ‘sentinel  
 21 event’ means any of the following:

22 “(i) An event that—

23 “(I) has resulted in an unantici-  
 24 pated death or major permanent loss  
 25 of function; and

1 “(II) is not related to the natural  
 2 course of the illness or underlying  
 3 condition of the patient.

4 “(ii) Any of the following events (even  
 5 if the outcome of the event did not result  
 6 in death or major permanent loss of func-  
 7 tion):

8 “(I) Surgery on the wrong pa-  
 9 tient or wrong body part.

10 “(II) Hemolytic transfusion reac-  
 11 tion involving administration of blood  
 12 or blood products that have blood  
 13 group incompatibilities.

14 “(III) Suicide of a patient in a  
 15 setting where the patient receives  
 16 around-the-clock care.

17 “(IV) Discharge of an infant to  
 18 the wrong family.

19 “(B) MAJOR PERMANENT LOSS OF FUNC-  
 20 TION.—For purposes of subparagraph (A), the  
 21 term ‘major permanent loss of function’ means  
 22 sensory, motor, physiologic, or intellectual im-  
 23 pairment that—

1 “(i) requires continued treatment or  
 2 imposes persistent major restrictions in ac-  
 3 tivities of daily living; and

4 “(ii) was not present—

5 “(I) on admission of the patient;

6 or

7 “(II) in the case of a patient who  
 8 was not admitted, at the initiation of  
 9 the provision of items or services to  
 10 the patient.

11 “ESTABLISHMENT OF PATIENT SAFETY PROGRAMS

12 “SEC. 1860B. (a) ESTABLISHMENT OF REQUIRE-  
 13 MENTS.—The Secretary shall establish requirements for  
 14 the establishment and implementation of patient safety  
 15 programs for providers of services participating in the  
 16 medicare program. Such requirements shall ensure that  
 17 a patient safety program—

18 “(1) targets applicable events;

19 “(2) targets at least 1 additional source of  
 20 health care errors, to be determined by the provider  
 21 of services, that contributes significantly to mor-  
 22 bidity and mortality in the service area of the pro-  
 23 vider or in patients receiving care from the provider;

24 “(3) analyzes the organizational processes,  
 25 functions, and services that are relevant to applica-  
 26 ble events;

1           “(4) utilizes active investigation of medical  
 2       records, medication utilization, laboratory results,  
 3       and other information to discover health care errors;  
 4       and

5           “(5) achieves significant measurable improve-  
 6       ment in rates of health care errors.

7       “(b) ESTABLISHMENT AND IMPLEMENTATION OF A  
 8       PATIENT SAFETY PROGRAM AS A CONDITION OF PARTICI-  
 9       PATION FOR PROVIDERS OF SERVICES.—The Secretary  
 10      shall ensure that each provider of services participating  
 11      in the medicare program (as a condition of such partici-  
 12      pation) has established and implemented a patient safety  
 13      program that is in compliance with the requirements es-  
 14      tablished under subsection (a).

15           “PATIENT SAFETY REPORTING SYSTEM

16       “SEC. 1860C. (a) ESTABLISHMENT.—The Secretary  
 17      shall establish a patient safety reporting system that pro-  
 18      vides for the collection and analysis of standardized infor-  
 19      mation concerning applicable events (including any root  
 20      cause analysis of, or corrective actions taken with respect  
 21      to, such events) under the medicare program.

22       “(b) REPORTS BY PROVIDERS OF SERVICES TO  
 23      AGENCIES AND ENTITIES.—

24           “(1) IN GENERAL.—Under the system estab-  
 25      lished under subsection (a), a provider of services  
 26      shall report each applicable event that occurs to an

1 individual while the individual is in the care or cus-  
 2 tody of the provider to—

3 “(A) the State health agency or other ap-  
 4 propriate State agency of the State in which the  
 5 provider of services is furnishing the services in-  
 6 volved;

7 “(B) in the case of a provider of services  
 8 participating in the medicare program as a re-  
 9 sult of accreditation by a national accrediting  
 10 body, the national accrediting body for the pro-  
 11 vider; and

12 “(C) the appropriate peer review organiza-  
 13 tion under part B of title XI.

14 “(2) STANDARDIZED DATA FOR REPORTS SUB-  
 15 MITTED TO AGENCIES AND ENTITIES.—

16 “(A) REPORTING STANDARDS.—The Sec-  
 17 retary, in consultation with the Agency for  
 18 Healthcare Research and Quality, national ac-  
 19 crediting organizations, provider and consumer  
 20 organizations, and peer review organizations,  
 21 shall, after consideration of existing reporting  
 22 systems and standards, establish and maintain  
 23 a core set of reporting standards to be used by  
 24 providers of services in submitting the reports



1 required under paragraph (1) to the agencies  
2 and entities described in such paragraph.

3 “(B) REQUIREMENTS FOR STANDARDS.—  
4 The reporting standards developed under sub-  
5 paragraph (A) shall—

6 “(i) require the inclusion of a descrip-  
7 tion of the applicable events occurring dur-  
8 ing the period covered by the report;

9 “(ii) except as provided in subpara-  
10 graph (D), require the inclusion of the root  
11 cause analysis of each applicable event in-  
12 cluded in the report and a description of  
13 any corrective action taken by the provider  
14 of services with respect to such event or  
15 any other measures necessary to prevent  
16 similar applicable events from occurring in  
17 the future;

18 “(iii) require that all provider of serv-  
19 ices provide the data required under this  
20 section;

21 “(iv) require that the privacy of indi-  
22 viduals whose treatment is the subject of a  
23 report is protected;

1 “(v) include a nomenclature and tax-  
2 onomy for the collection and reporting of  
3 such data; and

4 “(vi) meet such other requirements as  
5 the Secretary determines appropriate.

6 “(C) MEDICATION ERRORS.—In developing  
7 the reporting standards under this paragraph,  
8 the Secretary shall give immediate priority to  
9 the establishment of taxonomies and reporting  
10 protocols relating to medication errors.

11 “(D) WAIVER OF CERTAIN REPORTING RE-  
12 QUIREMENTS.—If determined appropriate by  
13 the Secretary, the standards developed under  
14 this paragraph may permit a provider of serv-  
15 ices to waive the reporting requirement de-  
16 scribed in subparagraph (B)(ii) with respect to  
17 an additional error event.

18 “(3) PHASE-IN OF REPORTING.—

19 “(A) IN GENERAL.—The Secretary shall  
20 establish a phase-in period with respect to the  
21 submission of data by various providers of serv-  
22 ices pursuant to paragraph (1).

23 “(B) REQUIREMENTS.—The phase-in pe-  
24 riod described in subparagraph (A) shall require  
25 that—

1 “(i) all hospitals submit the data re-  
2 quired under this section beginning not  
3 later than 1 year after the date of enact-  
4 ment of the Stop All Frequent Errors  
5 (SAFE) in Medicare and Medicaid Act of  
6 2000; and

7 “(ii) all other providers of services  
8 submit such data beginning at a time de-  
9 termined appropriate by the Secretary.

10 “(c) DESIGNATION OF AGENCY OR ENTITY.—

11 “(1) IN GENERAL.—Each provider of services  
12 shall designate 1 of the agencies or entities described  
13 in subsection (b)(1) to determine compliance with  
14 the patient safety reporting system established under  
15 this section with respect to applicable events for  
16 which reports are required under such subsection.

17 “(2) DISAPPROVAL BY SECRETARY.—

18 “(A) IN GENERAL.—The Secretary may  
19 disapprove the designation made under para-  
20 graph (1) if the Secretary determines such dis-  
21 approval to be appropriate.

22 “(B) DESIGNATION OF ANOTHER AGENCY  
23 OR ENTITY.—In the case of a disapproval under  
24 subparagraph (A), the provider of services shall  
25 designate another of the agencies or entities de-

1           scribed in subsection (b)(1) to have designated  
2           authority.

3           “(d) INVESTIGATION OF APPLICABLE EVENTS BY  
4 AGENCY OR ENTITY WITH DESIGNATED AUTHORITY.—  
5 The agency or entity designated by a provider of services  
6 under subsection (c) shall—

7           “(1) ensure that the provider of services, with  
8           respect to any reported applicable event—

9                   “(A) conducts an investigation of the ap-  
10                  plicable event;

11                   “(B) determines the root cause or causes  
12                  of the applicable event; and

13                   “(C) establishes and implements a time-  
14                  limited plan or strategy—

15                           “(i) to correct the problem or prob-  
16                          lems that resulted in the applicable event;

17                           “(ii) that leads to the reduction of the  
18                          risk of such event happening in the future;  
19                          and

20                           “(iii) that allows the agency or entity  
21                          to determine the appropriateness of the  
22                          root cause analyses and any corrective ac-  
23                          tions proposed or taken by the provider of  
24                          services; and

1           “(2) prepare and submit the reports required  
2           under subsection (e).

3           “(e) REPORTS TO THE SECRETARY BY AGENCY OR  
4           ENTITY WITH DESIGNATED AUTHORITY.—

5           “(1) IN GENERAL.—The agency or entity with  
6           designated authority shall submit a report con-  
7           taining the information described in paragraph (3)  
8           to the Secretary in such form and manner, and by  
9           such date, as the Secretary prescribes.

10           “(2) FREQUENCY.—The report described in  
11           paragraph (1) shall be submitted to the Secretary at  
12           regular intervals, but not less frequently than annu-  
13           ally.

14           “(3) INFORMATION TO BE REPORTED.—

15           “(A) IN GENERAL.—The report described  
16           in paragraph (1) shall include—

17                   “(i) a description of the applicable  
18                   events occurring during the period covered  
19                   by the report;

20                   “(ii) a description of any corrective  
21                   action taken by the providers of services  
22                   with respect to the applicable events or any  
23                   other measures necessary to prevent simi-  
24                   lar applicable events from occurring in the  
25                   future;

1 “(iii) a description of proposed sys-  
 2 tems changes identified as a result of anal-  
 3 ysis of events from multiple providers; and

4 “(iv) such additional information as  
 5 the Secretary determines to be essential to  
 6 ensure compliance with the requirements  
 7 of this section.

8 “(B) INFORMATION EXCLUDED.—The re-  
 9 port submitted under paragraph (1) shall not  
 10 identify any provider of services, practitioner or  
 11 other health care worker, or patient.

12 “(4) ADDITIONAL REPORTING REQUIREMENTS  
 13 WHEN A PROVIDER HAS BEEN IDENTIFIED AS HAV-  
 14 ING A PATTERN OF POOR PERFORMANCE.—

15 “(A) REPORT TO SECRETARY.—

16 “(i) IN GENERAL.—Notwithstanding  
 17 any other provision of law, in addition to  
 18 the report required under paragraph (1),  
 19 the agency or entity with designated au-  
 20 thority shall report to the Secretary the  
 21 name and address of any provider of serv-  
 22 ices with a pattern of poor performance.

23 “(ii) INFORMATION TO THE PUBLIC.—  
 24 The Secretary shall make the information  
 25 described in clause (i) available to the pub-

1           lic if the pattern of poor performance con-  
2           tinues for more than 2 years.

3           “(B) DETERMINATION OF PATTERN.—The  
4           agency or entity with designated authority shall  
5           determine if a pattern of poor performance ex-  
6           ists with respect to a provider of services in ac-  
7           cordance with the definition of pattern of poor  
8           performance developed by the Secretary under  
9           subparagraph (C).

10          “(C) DEVELOPMENT OF DEFINITION.—

11           “(i) IN GENERAL.—The Secretary, in  
12           consultation with the Agency for  
13           Healthcare Research and Quality, national  
14           accrediting organizations, provider and  
15           consumer organizations, and peer review  
16           organizations, shall develop a definition to  
17           identify a provider of services with a pat-  
18           tern of poor performance. In developing  
19           such definition, the Secretary shall ensure  
20           that a provider of services described in  
21           clause (ii) is deemed to be a provider of  
22           services with a pattern of poor perform-  
23           ance.

24           “(ii) PROVIDER DESCRIBED.—A pro-  
25           vider of services described in this clause is

1 a provider of services that has a pattern  
2 of—

3 “(I) failing to report applicable  
4 events pursuant to this part; or

5 “(II) except for events described  
6 in subsection (b)(2)(D), failing to im-  
7 plement corrective actions with re-  
8 spect to applicable events or signifi-  
9 cantly delaying such implementation.

10 “(D) EFFECTIVE DATE.—An agency or en-  
11 tity with designated authority shall not submit  
12 a report to the Secretary pursuant to this para-  
13 graph until the Secretary has established the  
14 definition under paragraph (C).

15 “(f) ENFORCEMENT OF REQUIREMENTS FOR ENTI-  
16 TIES.—

17 “(1) PART OF CONTRACT FOR PEER REVIEW  
18 ORGANIZATIONS.—Pursuant to section  
19 1154(a)(17)(A), the requirements under this part  
20 with respect to a peer review organization shall be  
21 considered to be requirements under a contract be-  
22 tween the Secretary and the organization under part  
23 B of title XI.

24 “(2) FAILURE OF ACCREDITING BODY TO COM-  
25 PLY WITH REQUIREMENTS.—If an accrediting body



1 refuses to comply with the requirements under this  
2 part, the Secretary, after notice to the accrediting  
3 body and opportunity to comply, may revoke the au-  
4 thority of the accrediting body to serve as an agent  
5 of the medicare or medicaid program for certifi-  
6 cation purposes.

7 “(3) FAILURE OF HEALTH DEPARTMENT OF A  
8 STATE TO COMPLY WITH REQUIREMENTS.—If a  
9 State health agency or other appropriate State agen-  
10 cy refuses to comply with the requirements under  
11 this part, the Secretary, after notice to the agency  
12 and opportunity to comply, shall revoke the ability  
13 of a provider of services to designate such agency as  
14 the agency with designated authority with respect to  
15 such provider pursuant to subsection (c).

16 “(g) LIMITATION ON USE OF INFORMATION.—

17 “(1) STATE.—Any State health agency or other  
18 appropriate State agency that receives information  
19 regarding applicable events with respect to a pro-  
20 vider of services pursuant to this part (or a con-  
21 gregate care provider pursuant to the application of  
22 this part to such a provider under title XIX) shall  
23 not permit such information to be utilized in con-  
24 junction with the survey, certification, or enforce-

1       ment process conducted by, or on behalf of, the  
2       agency with respect to such provider.

3               “(2) SECRETARY.—The Secretary shall not per-  
4       mit any information received by the Secretary re-  
5       garding applicable events with respect to a provider  
6       of services pursuant to this part (or a congregate  
7       care provider pursuant to the application of this part  
8       to such a provider under title XIX) to be utilized in  
9       conjunction with the survey, certification, or enforce-  
10      ment process conducted by, or on behalf of, the Sec-  
11      retary with respect to such provider.

12           “(h) ANALYSIS OF REPORTED INFORMATION BY THE  
13      SECRETARY.—The Secretary shall analyze the data re-  
14      ceived under this part with respect to the medicare pro-  
15      gram in a manner that permits the Secretary to identify  
16      pertinent patient safety issues that require more intensive  
17      analysis.

18           “(i) PROVISION OF INFORMATION TO CENTER FOR  
19      PATIENT SAFETY.—The Secretary shall provide the direc-  
20      tor of the Center for Patient Safety, established under sec-  
21      tion 5 of the Stop All Frequent Errors (SAFE) in Medi-  
22      care and Medicaid Act of 2000, with any information ob-  
23      tained under this part (or under title XIX pursuant to  
24      the application of this part to congregate care providers  
25      under such title) that the director of the Center deter-

1 mines is necessary in order to carry out the mission of  
 2 the Center.

3 “CONFIDENTIALITY AND PRIVACY PROTECTIONS

4 “SEC. 1860D. (a) CONFIDENTIALITY.—

5 “(1) IN GENERAL.—Notwithstanding any other  
 6 provision of law, any information (including any  
 7 data, reports, records, memoranda, analyses, state-  
 8 ments, and other communications) developed by or  
 9 on behalf of a provider of services with respect to an  
 10 applicable event pursuant to this part—

11 “(A) shall be privileged, strictly confiden-  
 12 tial, and may not be disclosed by any other per-  
 13 son to which such information is transferred  
 14 pursuant to this part without the authorization  
 15 of the provider of services; and

16 “(B) shall—

17 “(i) be protected from disclosure by  
 18 civil or administrative subpoena;

19 “(ii) not be subject to discovery or  
 20 otherwise in connection with a civil, crimi-  
 21 nal, or administrative proceeding;

22 “(iii) not be subject to disclosure pur-  
 23 suant to the Freedom of Information Act  
 24 (5 U.S.C. 552) or any other similar Fed-  
 25 eral or State statute or regulation; and

1 “(iv) not be admissible as evidence in  
2 any civil or administrative proceeding;  
3 without regard to whether such information is  
4 held by the provider of services or by another  
5 person to which such information was trans-  
6 ferred pursuant to this part.

7 “(2) RULES OF CONSTRUCTION.—Nothing in  
8 this subsection shall be construed as prohibiting—

9 “(A) subject to confidentiality laws, disclo-  
10 sure of a patient’s medical record;

11 “(B) an entity or agency from requiring a  
12 provider of services to transfer information to  
13 the entity or agency to the extent required by  
14 law;

15 “(C) an agency or entity described in sec-  
16 tion 1860C(b)(1), the Secretary, or the Center  
17 for Patient Safety from transferring informa-  
18 tion received pursuant to this part to another  
19 such agency or entity, the Secretary, or such  
20 Center; or

21 “(D) the Center for Patient Safety from  
22 releasing data received pursuant to this part in  
23 a form that does not identify or permit the  
24 identification of providers of services, practi-

1           tioners or other health care workers, or pa-  
2           tients.

3           “(b) PROTECTION OF PATIENT INFORMATION.—The  
4   Secretary shall establish procedures to ensure that the pri-  
5   vacy of individuals whose treatment is the subject of a re-  
6   port submitted under subsections (b) or (e) of section  
7   1860C is protected.

8           “(c) LIABILITY.—Nothing in this section shall be  
9   construed as limiting the liability of an individual, provider  
10   of services, agency, or entity for damages relating to the  
11   occurrence of an applicable event, including an applicable  
12   event that results in death.”.

13          (b) CONTRACT FOR PEER REVIEW ORGANIZATION.—

14               (1) IN GENERAL.—Section 1154(a) of the So-  
15   cial Security Act (42 U.S.C. 1320c–3(a)) is amended  
16   by adding at the end the following:

17               “(17) The organization shall—

18                       “(A) comply with the requirements for  
19   peer review organizations under part D of title  
20   XVIII; and

21                       “(B) assist providers of services (as de-  
22   fined in section 1860A(5)) and congregate care  
23   providers (as defined in section 1905(x)) in  
24   identifying health care errors by utilizing the  
25   clinical indicators that the Secretary, in con-

1           sultation with the Agency for Healthcare Re-  
 2           search and Quality, national accrediting organi-  
 3           zations, provider and consumer organizations,  
 4           and peer review organizations, determines are  
 5           most frequently associated with preventable  
 6           morbidity and mortality.”.

7           (2) EFFECTIVE DATE.—The amendment made  
 8           by this subsection shall apply to contracts entered  
 9           into or renewed on or after the date of enactment  
 10          of this Act.

11 **SEC. 4. IMPROVEMENT OF PATIENT SAFETY UNDER THE**  
 12 **MEDICAID PROGRAM.**

13          (a) STATE PLANS FOR MEDICAL ASSISTANCE.—Sec-  
 14          tion 1902(a) of the Social Security Act (42 U.S.C.  
 15          1396a(a)) is amended—

16               (1) in paragraph (64), by striking “and” at the  
 17               end;

18               (2) in paragraph (65), by striking the period  
 19               and inserting “; and”; and

20               (3) by inserting immediately after paragraph  
 21               (65) the following new paragraph:

22               “(66) provide that the State will ensure that  
 23               any congregate care provider (as defined in section  
 24               1905(x)) that provides services to an individual for  
 25               which medical assistance is available shall—

1           “(A) establish and implement a patient  
 2           safety program described in subsection (b) of  
 3           section 1860B in the same manner as a pro-  
 4           vider of services under that section is required  
 5           to establish and implement such a system; and

6           “(B) submit the reports required under  
 7           subsection (b) of section 1860C (relating to ap-  
 8           plicable events) in the same manner as a pro-  
 9           vider of services under that section is required  
 10          to submit such reports.”.

11          (b) DEFINITION OF CONGREGATE CARE PRO-  
 12          VIDER.—Section 1905 of the Social Security Act (42  
 13          U.S.C. 1396d) is amended by adding at the end the fol-  
 14          lowing new subsection:

15          “(x) The term ‘congregate care provider’ means an  
 16          entity that provides hospital services, nursing facility serv-  
 17          ices, services of intermediate care facilities for the men-  
 18          tally retarded, hospice care, residential treatment centers  
 19          for children, services in an institution for mental diseases,  
 20          inpatient psychiatric hospital services for individuals  
 21          under age 21, or congregate care services under a waiver  
 22          authorized under section 1915(c).”.

23          (c) APPLICATION OF MEDICARE PART D RULES AND  
 24          REQUIREMENTS TO CONGREGATE CARE PROVIDERS.—

1 Title XIX of the Social Security Act (42 U.S.C. 1396 et  
2 seq.) is amended—

3 (1) by redesignating section 1935 as section  
4 1936; and

5 (2) by inserting after section 1934 the following  
6 new section:

7 “APPLICATION OF MEDICARE PART D RULES AND  
8 REQUIREMENTS TO CONGREGATE CARE PROVIDERS

9 “SEC. 1935. The Secretary shall promulgate such  
10 regulations as are necessary in order to apply the rules  
11 and requirements that are applicable to providers of serv-  
12 ices under part D of title XVIII to congregate care pro-  
13 viders (as defined in section 1905(x)) pursuant to section  
14 1902(a)(66) and shall provide an analysis described in sec-  
15 tion 1860C(g) with respect to the program under this  
16 title.”.

17 **SEC. 5. ESTABLISHMENT OF THE CENTER FOR PATIENT**  
18 **SAFETY.**

19 (a) ESTABLISHMENT.—

20 (1) CENTER.—There is established within the  
21 Agency for Healthcare Research and Quality, a cen-  
22 ter to be known as the Center for Patient Safety (in  
23 this section referred to as the “Center”).

24 (2) DIRECTOR.—The Secretary of Health and  
25 Human Services shall appoint a director of the Cen-  
26 ter. The director shall administer the Center and



1        carry out the duties of the director under this sec-  
2        tion subject to the authority, direction, and control  
3        of the Secretary.

4        (b) MISSION.—The mission of the Center is to im-  
5        prove patient safety and reduce the incidence of errors in  
6        the provision of health care.

7        (c) DUTIES.—In carrying out the mission of the Cen-  
8        ter, the director of the Center shall provide for the fol-  
9        lowing:

10            (1) The establishment of national goals for pa-  
11            tient safety and mechanisms to track the progress of  
12            the Nation in meeting such goals.

13            (2) The provision of recommendations to the  
14            Secretary of Health and Human Services  
15            regarding—

16                    (A) the establishment of additional error  
17                    events under section 1860A(1) of the Social Se-  
18                    curity Act (as added by section 3); and

19                    (B) the development of a definition of a—

20                            (i) provider of services with a pattern  
21                            of poor performance under section  
22                            1860C(e)(3)(C) of the Social Security (as  
23                            so added); and

24                            (ii) congregate care provider with a  
25                            pattern of poor performance (by reason of

1           the application of such section to such a  
2           provider pursuant to section 1902(a)(66)  
3           of the Social Security Act (42 U.S.C.  
4           1396a(a)(66)) (as added by section 4)).

5           (3) The preparation and submission to the  
6           President and Congress of an annual report and rec-  
7           ommendations concerning patient safety.

8           (4) The development of knowledge and under-  
9           standing concerning errors in health care through—

10           (A) the development of a national health  
11           care patient safety research agenda;

12           (B) the provision of funding for dissemina-  
13           tion and communication activities to improve  
14           patient safety;

15           (C) the evaluation of methods for identi-  
16           fying and preventing health care errors; and

17           (D) the provision of funding for computer-  
18           ized decision support systems to reduce health  
19           care errors and to improve care.

20           (5) The dissemination of information con-  
21           cerning existing patient safety reporting programs.

22           (6) The conduct of activities to track the devel-  
23           opment of new, or modification of existing, patient  
24           safety reporting programs.

1           (7) The convening of panels of patient safety  
2       reporting program coordinators and users to evalu-  
3       ate reporting practices that are effective in improv-  
4       ing patient safety.

5           (8) The periodic assessment of whether addi-  
6       tional efforts are needed to—

7                (A) address gaps in patient safety informa-  
8       tion; and

9                (B) encourage organizations to voluntarily  
10      participate in patient safety reporting pro-  
11      grams.

12          (9) The provision of funding for pilot projects  
13      for the establishment or operation of new or innova-  
14      tive patient safety reporting systems.

15          (10) The provision of funding for pilot projects  
16      that reduce health care errors.

17          (11) The provision of funding for the review of  
18      existing databases of medical errors in order to iden-  
19      tify best practices.

20          (12) The provision of funding for research to  
21      identify the attributes of high-risk organizations and  
22      processes.

23          (13) The conduct of activities to encourage all  
24      entities and health care providers to demonstrate  
25      continuous improvements in patient safety to the

1 public and private purchasers of the health care  
 2 services provided by such entities or providers.

3 (14) The conduct of other activities determined  
 4 appropriate by the director of the Center.

5 (d) PROTECTION OF PATIENT INFORMATION.—The  
 6 director of the Center shall establish procedures to ensure  
 7 that the privacy of individuals whose treatment is de-  
 8 scribed in any information received by the director pursu-  
 9 ant to this part is protected.

10 **SEC. 6. GRANTS TO ESTABLISH PATIENT SAFETY PRO-**  
 11 **GRAMS.**

12 (a) IN GENERAL.—The director of the Center for Pa-  
 13 tient Safety (established under section 5) may award  
 14 grants to providers of services (as defined in section  
 15 1860A(5) of the Social Security Act (as added by section  
 16 3)), congregate care providers (as defined in section  
 17 1905(x) of such Act (42 U.S.C. 1396d(x)) (as added by  
 18 section 4)), and health professionals affiliated with such  
 19 providers of services or congregate care providers for the  
 20 establishment and operation of patient safety programs.

21 (b) APPLICATION.—To be eligible to receive a grant  
 22 under subsection (a), a provider of services, a congregate  
 23 care provider, or a health professional affiliated with such  
 24 a provider of services or congregate care provider shall  
 25 prepare and submit to the director of the Center an appli-

1 cation at such time, in such manner, and containing such  
2 information as the director may require.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated the following amounts  
5 to carry out this section:

6 (1) For fiscal year 2001, \$30,000,000.

7 (2) For fiscal year 2002, \$35,000,000.

8 (3) For fiscal year 2003, \$40,000,000.

9 (4) For each fiscal year thereafter, such sums  
10 as may be necessary.

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