

In the Senate of the United States,

July 22, 2004.

Resolved, That the bill from the House of Representatives (H.R. 663) entitled “An Act to amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety, and for other purposes.”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Patient Safety and*

3 *Quality Improvement Act of 2004”.*

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) *FINDINGS.*—Congress makes the following findings:

3 (1) *In 1999, the Institute of Medicine released a*
4 *report entitled To Err is Human that described med-*
5 *ical errors as the eighth leading cause of death in the*
6 *United States, with as many as 98,000 people dying*
7 *as a result of medical errors each year.*

8 (2) *To address these deaths and injuries due to*
9 *medical errors, the health care system must identify*
10 *and learn from such errors so that systems of care can*
11 *be improved.*

12 (3) *In their report, the Institute of Medicine*
13 *called on Congress to provide legal protections with*
14 *respect to information reported for the purposes of*
15 *quality improvement and patient safety.*

16 (4) *The Health, Education, Labor, and Pensions*
17 *Committee of the Senate held 4 hearings in the 106th*
18 *Congress and 1 hearing in the 107th Congress on pa-*
19 *tient safety where experts in the field supported the*
20 *recommendation of the Institute of Medicine for con-*
21 *gressional action.*

22 (5) *Myriad public and private patient safety*
23 *initiatives have begun. The Quality Interagency Co-*
24 *ordination Taskforce has recommended steps to im-*
25 *prove patient safety that may be taken by each Fed-*

1 *eral agency involved in health care and activities re-*
2 *lating to these steps are ongoing.*

3 *(6) The research on patient safety unequivocally*
4 *calls for a learning environment, rather than a puni-*
5 *tive environment, in order to improve patient safety.*

6 *(7) Voluntary data gathering systems are more*
7 *supportive than mandatory systems in creating the*
8 *learning environment referred to in paragraph (6) as*
9 *stated in the Institute of Medicine's report.*

10 *(8) Promising patient safety reporting systems*
11 *have been established throughout the United States*
12 *and the best ways to structure and use these systems*
13 *are currently being determined, largely through*
14 *projects funded by the Agency for Healthcare Research*
15 *and Quality.*

16 *(9) Many organizations currently collecting pa-*
17 *tient safety data have expressed a need for legal pro-*
18 *tections that will allow them to review protected in-*
19 *formation and collaborate in the development and im-*
20 *plementation of patient safety improvement strate-*
21 *gies. Currently, the State peer review protections are*
22 *inadequate to allow the sharing of information to pro-*
23 *mote patient safety.*

24 *(b) PURPOSES.—It is the purpose of this Act to—*

1 (1) *encourage a culture of safety and quality in*
2 *the United States health care system by providing for*
3 *legal protection of information reported voluntarily*
4 *for the purposes of quality improvement and patient*
5 *safety; and*

6 (2) *ensure accountability by raising standards*
7 *and expectations for continuous quality improvements*
8 *in patient safety.*

9 **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

10 *Title IX of the Public Health Service Act (42 U.S.C.*
11 *299 et seq.) is amended—*

12 (1) *in section 912(c), by inserting “, in accord-*
13 *ance with part C,” after “The Director shall”;*

14 (2) *by redesignating part C as part D;*

15 (3) *by redesignating sections 921 through 928, as*
16 *sections 931 through 938, respectively;*

17 (4) *in 934(d) (as so redesignated), by striking*
18 *the second sentence and inserting the following: “Pen-*
19 *alties provided for under this section shall be imposed*
20 *and collected by the Secretary using the administra-*
21 *tive and procedural processes used to impose and col-*
22 *lect civil money penalties under section 1128A of the*
23 *Social Security Act (other than subsections (a) and*
24 *(b), the second sentence of subsection (f), and sub-*
25 *sections (i), (m), and (n)), unless the Secretary deter-*

1 *mines that a modification of procedures would be*
 2 *more suitable or reasonable to carry out this sub-*
 3 *section and provides for such modification by regula-*
 4 *tion.”;*

5 *(5) in section 938(1) (as so redesignated), by*
 6 *striking “921” and inserting “931”; and*

7 *(6) by inserting after part B the following:*

8 **“PART C—PATIENT SAFETY IMPROVEMENT**

9 **“SEC. 921. DEFINITIONS.**

10 *“In this part:*

11 *“(1) NON-IDENTIFIABLE INFORMATION.—*

12 *“(A) IN GENERAL.—The term ‘non-identifi-*
 13 *able information’ means, with respect to infor-*
 14 *mation, that the information is presented in a*
 15 *form and manner that prevents the identifica-*
 16 *tion of a provider, a patient, or a reporter of pa-*
 17 *tient safety data.*

18 *“(B) IDENTIFIABILITY OF PATIENT.—For*
 19 *purposes of subparagraph (A), the term ‘pre-*
 20 *sented in a form and manner that prevents the*
 21 *identification of a patient’ means, with respect*
 22 *to information that has been subject to rules pro-*
 23 *mulgated pursuant to section 264(c) of the*
 24 *Health Insurance Portability and Accountability*
 25 *Act of 1996 (42 U.S.C. 1320d–2 note), that the*

1 *information has been de-identified so that it is*
2 *no longer individually identifiable health infor-*
3 *mation as defined in such rules.*

4 “(2) *PATIENT SAFETY DATA.*—

5 “(A) *IN GENERAL.*—*The term ‘patient safe-*
6 *ty data’ means—*

7 “(i) *any data, reports, records, memo-*
8 *randa, analyses (such as root cause anal-*
9 *yses), or written or oral statements that*
10 *are—*

11 “(I) *collected or developed by a*
12 *provider for reporting to a patient*
13 *safety organization, provided that they*
14 *are reported to the patient safety orga-*
15 *nization within 60 days;*

16 “(II) *requested by a patient safety*
17 *organization (including the contents of*
18 *such request), if they are reported to*
19 *the patient safety organization within*
20 *60 days;*

21 “(III) *reported to a provider by a*
22 *patient safety organization; or*

23 “(IV) *collected by a patient safety*
24 *organization from another patient safe-*

1 *ty organization, or developed by a pa-*
2 *tient safety organization;*
3 *that could result in improved patient safety,*
4 *health care quality, or health care outcomes;*
5 *or*

6 *“(ii) any deliberative work or process*
7 *with respect to any patient safety data de-*
8 *scribed in clause (i).*

9 *“(B) LIMITATION.—*

10 *“(i) COLLECTION.—If the original ma-*
11 *terial from which any data, reports, records,*
12 *memoranda, analyses (such as root case*
13 *analyses), or written or oral statements re-*
14 *ferred to in subclause (I) or (IV) of sub-*
15 *paragraph (A)(i) are collected and is not*
16 *patient safety data, the act of such collec-*
17 *tion shall not make such original material*
18 *patient safety data for purposes of this*
19 *part.*

20 *“(ii) SEPARATE DATA.—The term ‘pa-*
21 *tient safety data’ shall not include informa-*
22 *tion (including a patient’s medical record,*
23 *billing and discharge information or any*
24 *other patient or provider record) that is col-*
25 *lected or developed separately from and that*

1 *exists separately from patient safety data.*
2 *Such separate information or a copy thereof*
3 *submitted to a patient safety organization*
4 *shall not itself be considered as patient safe-*
5 *ty data. Nothing in this part, except for sec-*
6 *tion 922(f)(1), shall be construed to limit—*

7 *“(I) the discovery of or admissi-*
8 *bility of information described in this*
9 *subparagraph in a criminal, civil, or*
10 *administrative proceeding;*

11 *“(II) the reporting of information*
12 *described in this subparagraph to a*
13 *Federal, State, or local governmental*
14 *agency for public health surveillance,*
15 *investigation, or other public health*
16 *purposes or health oversight purposes;*
17 *or*

18 *“(III) a provider’s recordkeeping*
19 *obligation with respect to information*
20 *described in this subparagraph under*
21 *Federal, State, or local law.*

22 *“(3) PATIENT SAFETY ORGANIZATION.—The term*
23 *‘patient safety organization’ means a private or pub-*
24 *lic entity or component thereof that is currently listed*
25 *by the Secretary pursuant to section 924(c).*

1 “(4) *PATIENT SAFETY ORGANIZATION ACTIVITIES.*—*The term ‘patient safety organization activities’ means the following activities, which are deemed*
2 *to be necessary for the proper management and ad-*
3 *ministration of a patient safety organization:*

6 “(A) *The conduct, as its primary activity,*
7 *of efforts to improve patient safety and the qual-*
8 *ity of health care delivery.*

9 “(B) *The collection and analysis of patient*
10 *safety data that are submitted by more than one*
11 *provider.*

12 “(C) *The development and dissemination of*
13 *information to providers with respect to improv-*
14 *ing patient safety, such as recommendations,*
15 *protocols, or information regarding best prac-*
16 *tices.*

17 “(D) *The utilization of patient safety data*
18 *for the purposes of encouraging a culture of safe-*
19 *ty and of providing direct feedback and assist-*
20 *ance to providers to effectively minimize patient*
21 *risk.*

22 “(E) *The maintenance of procedures to pre-*
23 *serve confidentiality with respect to patient safe-*
24 *ty data.*

1 “(F) *The provision of appropriate security*
2 *measures with respect to patient safety data.*

3 “(G) *The utilization of qualified staff.*

4 “(5) *PERSON.—The term ‘person’ includes Fed-*
5 *eral, State, and local government agencies.*

6 “(6) *PROVIDER.—The term ‘provider’ means—*

7 “(A) *a person licensed or otherwise author-*
8 *ized under State law to provide health care serv-*
9 *ices, including—*

10 “(i) *a hospital, nursing facility, com-*
11 *prehensive outpatient rehabilitation facility,*
12 *home health agency, hospice program, renal*
13 *dialysis facility, ambulatory surgical center,*
14 *pharmacy, physician or health care practi-*
15 *tioner’s office, long term care facility, be-*
16 *havior health residential treatment facility,*
17 *clinical laboratory, or health center; or*

18 “(ii) *a physician, physician assistant,*
19 *nurse practitioner, clinical nurse specialist,*
20 *certified registered nurse anesthetist, cer-*
21 *tified nurse midwife, psychologist, certified*
22 *social worker, registered dietitian or nutri-*
23 *tion professional, physical or occupational*
24 *therapist, pharmacist, or other individual*
25 *health care practitioner; or*

1 “(B) any other person specified in regula-
2 tions promulgated by the Secretary.

3 **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**
4 **TIONS.**

5 “(a) *PRIVILEGE.*—Notwithstanding any other provi-
6 sion of Federal, State, or local law, patient safety data shall
7 be privileged and, subject to the provisions of subsection
8 (c)(1), shall not be—

9 “(1) subject to a Federal, State, or local civil,
10 criminal, or administrative subpoena;

11 “(2) subject to discovery in connection with a
12 Federal, State, or local civil, criminal, or administra-
13 tive proceeding;

14 “(3) disclosed pursuant to section 552 of title 5,
15 United States Code (commonly known as the Freedom
16 of Information Act) or any other similar Federal,
17 State, or local law;

18 “(4) admitted as evidence or otherwise disclosed
19 in any Federal, State, or local civil, criminal, or ad-
20 ministrative proceeding; or

21 “(5) utilized in a disciplinary proceeding
22 against a provider.

23 “(b) *CONFIDENTIALITY.*—Notwithstanding any other
24 provision of Federal, State, or local law, and subject to the

1 *provisions of subsections (c) and (d), patient safety data*
2 *shall be confidential and shall not be disclosed.*

3 “(c) *EXCEPTIONS TO PRIVILEGE AND CONFIDEN-*
4 *TIALITY.—Nothing in this section shall be construed to pro-*
5 *hibit one or more of the following uses or disclosures:*

6 “(1) *Disclosure by a provider or patient safety*
7 *organization of relevant patient safety data for use in*
8 *a criminal proceeding only after a court makes an in*
9 *camera determination that such patient safety data*
10 *contains evidence of a wanton and criminal act to di-*
11 *rectly harm the patient.*

12 “(2) *Voluntary disclosure of non-identifiable pa-*
13 *tient safety data by a provider or a patient safety or-*
14 *ganization.*

15 “(d) *PROTECTED DISCLOSURE AND USE OF INFORMA-*
16 *TION.—Nothing in this section shall be construed to prohibit*
17 *one or more of the following uses or disclosures:*

18 “(1) *Disclosure of patient safety data by a per-*
19 *son that is a provider, a patient safety organization,*
20 *or a contractor of a provider or patient safety organi-*
21 *zation, to another such person, to carry out patient*
22 *safety organization activities.*

23 “(2) *Disclosure of patient safety data by a pro-*
24 *vider or patient safety organization to grantees or*
25 *contractors carrying out patient safety research, eval-*

1 *uation, or demonstration projects authorized by the*
2 *Director.*

3 *“(3) Disclosure of patient safety data by a pro-*
4 *vider to an accrediting body that accredits that pro-*
5 *vider.*

6 *“(4) Voluntary disclosure of patient safety data*
7 *by a patient safety organization to the Secretary for*
8 *public health surveillance if the consent of each pro-*
9 *vider identified in, or providing, such data is ob-*
10 *tained prior to such disclosure. Nothing in the pre-*
11 *ceding sentence shall be construed to prevent the re-*
12 *lease of patient safety data that is provided by, or*
13 *that relates solely to, a provider from which the con-*
14 *sent described in such sentence is obtained because one*
15 *or more other providers do not provide such consent*
16 *with respect to the disclosure of patient safety data*
17 *that relates to such nonconsenting providers. Consent*
18 *for the future release of patient safety data for such*
19 *purposes may be requested by the patient safety orga-*
20 *nization at the time the data is submitted.*

21 *“(5) Voluntary disclosure of patient safety data*
22 *by a patient safety organization to State or local gov-*
23 *ernment agencies for public health surveillance if the*
24 *consent of each provider identified in, or providing,*
25 *such data is obtained prior to such disclosure. Noth-*

1 *ing in the preceding sentence shall be construed to*
2 *prevent the release of patient safety data that is pro-*
3 *vided by, or that relates solely to, a provider from*
4 *which the consent described in such sentence is ob-*
5 *tained because one or more other providers do not*
6 *provide such consent with respect to the disclosure of*
7 *patient safety data that relates to such nonconsenting*
8 *providers. Consent for the future release of patient*
9 *safety data for such purposes may be requested by the*
10 *patient safety organization at the time the data is*
11 *submitted.*

12 *“(e) CONTINUED PROTECTION OF INFORMATION AFTER*
13 *DISCLOSURE.—*

14 *“(1) IN GENERAL.—Except as provided in para-*
15 *graph (2), patient safety data that is used or dis-*
16 *closed shall continue to be privileged and confidential*
17 *as provided for in subsections (a) and (b), and the*
18 *provisions of such subsections shall apply to such*
19 *data in the possession or control of—*

20 *“(A) a provider or patient safety organiza-*
21 *tion that possessed such data before the use or*
22 *disclosure; or*

23 *“(B) a person to whom such data was dis-*
24 *closed.*

1 “(2) *EXCEPTION.*—*Notwithstanding paragraph*
2 *(1), and subject to paragraph (3)—*

3 “(A) *if patient safety data is used or dis-*
4 *closed as provided for in subsection (c)(1), and*
5 *such use or disclosure is in open court, the con-*
6 *fidentiality protections provided for in sub-*
7 *section (b) shall no longer apply to such data;*
8 *and*

9 “(B) *if patient safety data is used or dis-*
10 *closed as provided for in subsection (c)(2), the*
11 *privilege and confidentiality protections pro-*
12 *vided for in subsections (a) and (b) shall no*
13 *longer apply to such data.*

14 “(3) *CONSTRUCTION.*—*Paragraph (2) shall not*
15 *be construed as terminating or limiting the privilege*
16 *or confidentiality protections provided for in sub-*
17 *section (a) or (b) with respect to data other than the*
18 *specific data used or disclosed as provided for in sub-*
19 *section (c).*

20 “(f) *LIMITATION ON ACTIONS.*—

21 “(1) *PATIENT SAFETY ORGANIZATIONS.*—*Except*
22 *to enforce disclosures pursuant to subsection (c)(1), no*
23 *action may be brought or process served against a pa-*
24 *tient safety organization to compel disclosure of infor-*
25 *mation collected or developed under this part whether*

1 *or not such information is patient safety data unless*
2 *such information is specifically identified, is not pa-*
3 *tient safety data, and cannot otherwise be obtained.*

4 *“(2) PROVIDERS.—An accrediting body shall not*
5 *take an accrediting action against a provider based*
6 *on the good faith participation of the provider in the*
7 *collection, development, reporting, or maintenance of*
8 *patient safety data in accordance with this part. An*
9 *accrediting body may not require a provider to reveal*
10 *its communications with any patient safety organiza-*
11 *tion established in accordance with this part.*

12 *“(g) REPORTER PROTECTION.—*

13 *“(1) IN GENERAL.—A provider may not take an*
14 *adverse employment action, as described in para-*
15 *graph (2), against an individual based upon the fact*
16 *that the individual in good faith reported*
17 *information—*

18 *“(A) to the provider with the intention of*
19 *having the information reported to a patient*
20 *safety organization; or*

21 *“(B) directly to a patient safety organiza-*
22 *tion.*

23 *“(2) ADVERSE EMPLOYMENT ACTION.—For pur-*
24 *poses of this subsection, an ‘adverse employment ac-*
25 *tion’ includes—*

1 “(A) *loss of employment, the failure to pro-*
2 *mote an individual, or the failure to provide any*
3 *other employment-related benefit for which the*
4 *individual would otherwise be eligible; or*

5 “(B) *an adverse evaluation or decision*
6 *made in relation to accreditation, certification,*
7 *credentialing, or licensing of the individual.*

8 “(h) *ENFORCEMENT.—*

9 “(1) *PROHIBITION.—Except as provided in sub-*
10 *sections (c) and (d) and as otherwise provided for in*
11 *this section, it shall be unlawful for any person to*
12 *negligently or intentionally disclose any patient safe-*
13 *ty data, and any such person shall, upon adjudica-*
14 *tion, be assessed in accordance with section 934(d).*

15 “(2) *RELATION TO HIPAA.—The penalty pro-*
16 *vided for under paragraph (1) shall not apply if the*
17 *defendant would otherwise be subject to a penalty*
18 *under the regulations promulgated under section*
19 *264(c) of the Health Insurance Portability and Ac-*
20 *countability Act of 1996 (42 U.S.C. 1320d–2 note) or*
21 *under section 1176 of the Social Security Act (42*
22 *U.S.C. 1320d–5) for the same disclosure.*

23 “(3) *EQUITABLE RELIEF.—*

24 “(A) *IN GENERAL.—Without limiting rem-*
25 *edies available to other parties, a civil action*

1 *may be brought by any aggrieved individual to*
2 *enjoin any act or practice that violates sub-*
3 *section (g) and to obtain other appropriate equi-*
4 *table relief (including reinstatement, back pay,*
5 *and restoration of benefits) to redress such viola-*
6 *tion.*

7 “(B) *AGAINST STATE EMPLOYEES.*—*An en-*
8 *tity that is a State or an agency of a State gov-*
9 *ernment may not assert the privilege described*
10 *in subsection (a) unless before the time of the as-*
11 *sertion, the entity or, in the case of and with re-*
12 *spect to an agency, the State has consented to be*
13 *subject to an action as described by this para-*
14 *graph, and that consent has remained in effect.*

15 “(i) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
16 *tion shall be construed to—*

17 “(1) *limit other privileges that are available*
18 *under Federal, State, or local laws that provide great-*
19 *er confidentiality protections or privileges than the*
20 *privilege and confidentiality protections provided for*
21 *in this section;*

22 “(2) *limit, alter, or affect the requirements of*
23 *Federal, State, or local law pertaining to information*
24 *that is not privileged or confidential under this sec-*
25 *tion;*

1 “(3) alter or affect the implementation of any
2 provision of section 264(c) of the Health Insurance
3 Portability and Accountability Act of 1996 (Public
4 Law 104–191; 110 Stat. 2033), section 1176 of the
5 Social Security Act (42 U.S.C. 1320d–5), or any reg-
6 ulation promulgated under such sections;

7 “(4) limit the authority of any provider, patient
8 safety organization, or other person to enter into a
9 contract requiring greater confidentiality or dele-
10 gating authority to make a disclosure or use in ac-
11 cordance with subsection (c) or (d); and

12 “(5) prohibit a provider from reporting a crime
13 to law enforcement authorities, regardless of whether
14 knowledge of the existence of, or the description of, the
15 crime is based on patient safety data, so long as the
16 provider does not disclose patient safety data in mak-
17 ing such report.

18 **“SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.**

19 “(a) *IN GENERAL.*—The Secretary shall maintain a
20 patient safety network of databases that provides an inter-
21 active evidence-based management resource for providers,
22 patient safety organizations, and other persons. The net-
23 work of databases shall have the capacity to accept, aggre-
24 gate, and analyze nonidentifiable patient safety data volun-

1 tarily reported by patient safety organizations, providers,
2 or other persons.

3 “(b) *NETWORK OF DATABASE STANDARDS.*—*The Sec-*
4 *retary may determine common formats for the reporting to*
5 *the patient safety network of databases maintained under*
6 *subsection (a) of nonidentifiable patient safety data, includ-*
7 *ing necessary data elements, common and consistent defini-*
8 *tions, and a standardized computer interface for the proc-*
9 *essing of such data. To the extent practicable, such stand-*
10 *ards shall be consistent with the administrative simplifica-*
11 *tion provisions of Part C of title XI of the Social Security*
12 *Act.*

13 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**
14 **CATION AND LISTING.**

15 “(a) *CERTIFICATION.*—

16 “(1) *INITIAL CERTIFICATION.*—*Except as pro-*
17 *vided in paragraph (2), an entity that seeks to be a*
18 *patient safety organization shall submit an initial*
19 *certification to the Secretary that the entity intends*
20 *to perform the patient safety organization activities.*

21 “(2) *DELAYED CERTIFICATION OF COLLECTION*
22 *FROM MORE THAN ONE PROVIDER.*—*An entity that*
23 *seeks to be a patient safety organization may—*

24 “(A) *submit an initial certification that it*
25 *intends to perform patient safety organization*

1 *activities other than the activities described in*
2 *subparagraph (B) of section 921(4); and*

3 “(B) *within 2 years of submitting the ini-*
4 *tial certification under subparagraph (A), sub-*
5 *mit a supplemental certification that it performs*
6 *the patient safety organization activities de-*
7 *scribed in subparagraphs (A) through (F) of sec-*
8 *tion 921(4).*

9 “(3) *EXPIRATION AND RENEWAL.—*

10 “(A) *EXPIRATION.—An initial certification*
11 *under paragraph (1) or (2)(A) shall expire on*
12 *the date that is 3 years after it is submitted.*

13 “(B) *RENEWAL.—*

14 “(i) *IN GENERAL.—An entity that*
15 *seeks to remain a patient safety organiza-*
16 *tion after the expiration of an initial cer-*
17 *tification under paragraph (1) or (2)(A)*
18 *shall, within the 3-year period described in*
19 *subparagraph (A), submit a renewal certifi-*
20 *cation to the Secretary that the entity per-*
21 *forms the patient safety organization activi-*
22 *ties described in section 921(4).*

23 “(ii) *TERM OF RENEWAL.—A renewal*
24 *certification under clause (i) shall expire on*
25 *the date that is 3 years after the date on*

1 *which it is submitted, and may be renewed*
2 *in the same manner as an initial certifi-*
3 *cation.*

4 “(b) *ACCEPTANCE OF CERTIFICATION.*—*Upon the sub-*
5 *mission by an organization of an initial certification pur-*
6 *suant to subsection (a)(1) or (a)(2)(A), a supplemental cer-*
7 *tification pursuant to subsection (a)(2)(B), or a renewal*
8 *certification pursuant to subsection (a)(3)(B), the Secretary*
9 *shall review such certification and—*

10 “(1) *if such certification meets the requirements*
11 *of subsection (a)(1), (a)(2)(A), (a)(2)(B), or (a)(3)(B),*
12 *as applicable, the Secretary shall notify the organiza-*
13 *tion that such certification is accepted; or*

14 “(2) *if such certification does not meet such re-*
15 *quirements, as applicable, the Secretary shall notify*
16 *the organization that such certification is not accept-*
17 *ed and the reasons therefor.*

18 “(c) *LISTING.*—

19 “(1) *IN GENERAL.*—*Except as otherwise provided*
20 *in this subsection, the Secretary shall compile and*
21 *maintain a current listing of patient safety organiza-*
22 *tions with respect to which the Secretary has accepted*
23 *a certification pursuant to subsection (b).*

24 “(2) *REMOVAL FROM LISTING.*—*The Secretary*
25 *shall remove from the listing under paragraph (1)—*

1 “(A) an entity with respect to which the
2 Secretary has accepted an initial certification
3 pursuant to subsection (a)(2)(A) and which does
4 not submit a supplemental certification pursu-
5 ant to subsection (a)(2)(B) that is accepted by
6 the Secretary;

7 “(B) an entity whose certification expires
8 and which does not submit a renewal applica-
9 tion that is accepted by the Secretary; and

10 “(C) an entity with respect to which the
11 Secretary revokes the Secretary’s acceptance of
12 the entity’s certification, pursuant to subsection
13 (d).

14 “(d) REVOCATION OF ACCEPTANCE.—

15 “(1) IN GENERAL.—Except as provided in para-
16 graph (2), if the Secretary determines (through a re-
17 view of patient safety organization activities) that a
18 patient safety organization does not perform one of
19 the patient safety organization activities described in
20 subparagraph (A) through (F) of section 921(4), the
21 Secretary may, after notice and an opportunity for a
22 hearing, revoke the Secretary’s acceptance of the cer-
23 tification of such organization.

24 “(2) DELAYED CERTIFICATION OF COLLECTION
25 FROM MORE THAN ONE PROVIDER.—A revocation

1 *under paragraph (1) may not be based on a deter-*
2 *mination that the organization does not perform the*
3 *activity described in section 921(4)(B) if—*

4 *“(A) the listing of the organization is based*
5 *on its submittal of an initial certification under*
6 *subsection (a)(2)(A);*

7 *“(B) the organization has not submitted a*
8 *supplemental certification under subsection*
9 *(a)(2)(B); and*

10 *“(C) the 2-year period described in sub-*
11 *section (a)(2)(B) has not expired.*

12 *“(e) NOTIFICATION OF REVOCATION OR REMOVAL*
13 *FROM LISTING.—*

14 *“(1) SUPPLYING CONFIRMATION OF NOTIFICA-*
15 *TION TO PROVIDERS.—Within 15 days of a revocation*
16 *under subsection (d)(1), a patient safety organization*
17 *shall submit to the Secretary a confirmation that the*
18 *organization has taken all reasonable actions to no-*
19 *tify each provider whose patient safety data is col-*
20 *lected or analyzed by the organization of such revoca-*
21 *tion.*

22 *“(2) PUBLICATION.—Upon the revocation of an*
23 *acceptance of an organization’s certification under*
24 *subsection (d)(1), or upon the removal of an organiza-*
25 *tion from the listing under subsection (c)(2), the Sec-*

1 *retary shall publish notice of the revocation or re-*
2 *moval in the Federal Register.*

3 “(f) *STATUS OF DATA AFTER REMOVAL FROM LIST-*
4 *ING.—*

5 “(1) *NEW DATA.—With respect to the privilege*
6 *and confidentiality protections described in section*
7 *922, data submitted to an organization within 30*
8 *days after the organization is removed from the list-*
9 *ing under subsection (c)(2) shall have the same status*
10 *as data submitted while the organization was still*
11 *listed.*

12 “(2) *PROTECTION TO CONTINUE TO APPLY.—If*
13 *the privilege and confidentiality protections described*
14 *in section 922 applied to data while an organization*
15 *was listed, or during the 30-day period described in*
16 *paragraph (1), such protections shall continue to*
17 *apply to such data after the organization is removed*
18 *from the listing under subsection (c)(2).*

19 “(g) *DISPOSITION OF DATA.—If the Secretary removes*
20 *an organization from the listing as provided for in sub-*
21 *section (c)(2), with respect to the patient safety data that*
22 *the organization received from providers, the organization*
23 *shall—*

1 “(1) with the approval of the provider and an-
2 other patient safety organization, transfer such data
3 to such other organization;

4 “(2) return such data to the person that sub-
5 mitted the data; or

6 “(3) if returning such data to such person is not
7 practicable, destroy such data.

8 **“SEC. 925. TECHNICAL ASSISTANCE.**

9 *“The Secretary, acting through the Director, may pro-
10 vide technical assistance to patient safety organizations, in-
11 cluding convening annual meetings for patient safety orga-
12 nizations to discuss methodology, communication, data col-
13 lection, or privacy concerns.*

14 **“SEC. 926. PROMOTING THE INTEROPERABILITY OF**
15 **HEALTH CARE INFORMATION TECHNOLOGY**
16 **SYSTEMS.**

17 *“(a) DEVELOPMENT.—Not later than 36 months after
18 the date of enactment of the Patient Safety and Quality
19 Improvement Act of 2004, the Secretary shall develop or
20 adopt voluntary standards that promote the electronic ex-
21 change of health care information.*

22 *“(b) UPDATES.—The Secretary shall provide for the
23 ongoing review and periodic updating of the standards de-
24 veloped under subsection (a).*

1 “(c) *DISSEMINATION.*—*The Secretary shall provide for*
2 *the dissemination of the standards developed and updated*
3 *under this section.*”

4 “**SEC. 927. AUTHORIZATION OF APPROPRIATIONS.**”

5 “*There is authorized to be appropriated such sums as*
6 *may be necessary to carry out this part.*”

7 **SEC. 4. STUDIES AND REPORTS.**

8 (a) *IN GENERAL.*—*The Secretary of Health and*
9 *Human Services shall enter into a contract (based upon*
10 *a competitive contracting process) with an appropriate re-*
11 *search organization for the conduct of a study to assess the*
12 *impact of medical technologies and therapies on patient*
13 *safety, patient benefit, health care quality, and the costs of*
14 *care as well as productivity growth. Such study shall*
15 *examine—*

16 (1) *the extent to which factors, such as the use*
17 *of labor and technological advances, have contributed*
18 *to increases in the share of the gross domestic product*
19 *that is devoted to health care and the impact of med-*
20 *ical technologies and therapies on such increases;*

21 (2) *the extent to which early and appropriate in-*
22 *troduction and integration of innovative medical*
23 *technologies and therapies may affect the overall pro-*
24 *ductivity and quality of the health care delivery sys-*
25 *tems of the United States; and*

1 (3) *the relationship of such medical technologies*
2 *and therapies to patient safety, patient benefit, health*
3 *care quality, and cost of care.*

4 (b) *REPORT.—Not later than 18 months after the date*
5 *of enactment of this Act, the Secretary of Health and*
6 *Human Services shall prepare and submit to the appro-*
7 *priate committees of Congress a report containing the re-*
8 *sults of the study conducted under subsection (a).*

Attest:

Secretary.

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2^D SESSION

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AMENDMENT