

109TH CONGRESS  
1ST SESSION

# S. 544

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 effect patient safety.

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## IN THE SENATE OF THE UNITED STATES

MARCH 8, 2005

Mr. JEFFORDS (for himself, Mr. GREGG, Mr. ENZI, Mr. BINGAMAN, Mr. FRIST, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

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 effect patient safety.

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 “Patient Safety and  
5 Quality Improvement Act of 2005”.

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

2 (a) FINDINGS.—Congress makes the following find-  
3 ings:

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

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

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

17 (4) The Health, Education, Labor, and Pen-  
18 sions Committee of the Senate held 4 hearings in  
19 the 106th Congress and 1 hearing in the 107th Con-  
20 gress on patient safety where experts in the field  
21 supported the recommendation of the Institute of  
22 Medicine for congressional action.

23 (5) Myriad public and private patient safety ini-  
24 tiatives have begun. The Quality Interagency Coordi-  
25 nation Taskforce has recommended steps to improve  
26 patient safety that may be taken by each Federal

1 agency involved in health care and activities relating  
2 to these steps are ongoing.

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

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

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

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

25 (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  
3 for legal protection of information reported volun-  
4 tarily for the purposes of quality improvement and  
5 patient safety; and

6           (2) ensure accountability by raising standards  
7 and expectations for continuous quality improve-  
8 ments 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,  
16 as sections 931 through 938, respectively;

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

1 the Secretary determines that a modification of pro-  
 2 cedures would be more suitable or reasonable to  
 3 carry out this subsection and provides for such  
 4 modification by regulation.”;

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-identi-  
 13 fiable 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  
 17 patient 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  
 23 promulgated 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  
6 safety 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 or-  
15 ganization within 60 days;

16 “(II) requested by a patient safe-  
17 ty organization (including the con-  
18 tents of such request), if they are re-  
19 ported to the patient safety organiza-  
20 tion within 60 days;

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

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

1 safety organization, or developed by a  
2 patient safety organization;  
3 that could result in improved patient safe-  
4 ty, health care quality, or health care out-  
5 comes; 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  
11 material from which any data, reports,  
12 records, memoranda, analyses (such as  
13 root case analyses), or written or oral  
14 statements referred to in subclause (I) or  
15 (IV) of subparagraph (A)(i) are collected  
16 and is not patient safety data, the act of  
17 such collection shall not make such original  
18 material patient safety data for purposes  
19 of this part.

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

1 from and that exists separately from pa-  
2 tient safety data. Such separate informa-  
3 tion or a copy thereof submitted to a pa-  
4 tient safety organization shall not itself be  
5 considered as patient safety data. Nothing  
6 in this part, except for section 922(f)(1),  
7 shall be construed to limit—

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

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

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

23 “(3) PATIENT SAFETY ORGANIZATION.—The  
24 term ‘patient safety organization’ means a private or



1 public entity or component thereof that is currently  
2 listed by the Secretary pursuant to section 924(c).

3 “(4) PATIENT SAFETY ORGANIZATION ACTIVITIES.—The term ‘patient safety organization activities’ means the following activities, which are  
4 deemed to be necessary for the proper management  
5 and administration of a patient safety organization:  
6

7  
8 “(A) The conduct, as its primary activity,  
9 of efforts to improve patient safety and the  
10 quality of health care delivery.

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

14 “(C) The development and dissemination  
15 of information to providers with respect to im-  
16 proving patient safety, such as recommenda-  
17 tions, protocols, or information regarding best  
18 practices.

19 “(D) The utilization of patient safety data  
20 for the purposes of encouraging a culture of  
21 safety and of providing direct feedback and as-  
22 sistance to providers to effectively minimize pa-  
23 tient risk.

1           “(E) The maintenance of procedures to  
2 preserve confidentiality with respect to patient  
3 safety data.

4           “(F) The provision of appropriate security  
5 measures with respect to patient safety data.

6           “(G) The utilization of qualified staff.

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

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

10           “(A) a person licensed or otherwise author-  
11 ized under State law to provide health care  
12 services, including—

13           “(i) a hospital, nursing facility, com-  
14 prehensive outpatient rehabilitation facil-  
15 ity, home health agency, hospice program,  
16 renal dialysis facility, ambulatory surgical  
17 center, pharmacy, physician or health care  
18 practitioner’s office, long term care facility,  
19 behavior health residential treatment facil-  
20 ity, clinical laboratory, or health center; or

21           “(ii) a physician, physician assistant,  
22 nurse practitioner, clinical nurse specialist,  
23 certified registered nurse anesthetist, cer-  
24 tified nurse midwife, psychologist, certified  
25 social worker, registered dietitian or nutri-

1           tion professional, physical or occupational  
2           therapist, pharmacist, or other individual  
3           health care practitioner; or

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

6 **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**  
7           **TIONS.**

8           “(a) PRIVILEGE.—Notwithstanding any other provi-  
9           sion of Federal, State, or local law, patient safety data  
10          shall be privileged and, subject to the provisions of sub-  
11          section (c)(1), shall not be—

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

14           “(2) subject to discovery in connection with a  
15          Federal, State, or local civil, criminal, or administra-  
16          tive proceeding;

17           “(3) disclosed pursuant to section 552 of title  
18          5, United States Code (commonly known as the  
19          Freedom of Information Act) or any other similar  
20          Federal, State, or local law;

21           “(4) admitted as evidence or otherwise disclosed  
22          in any Federal, State, or local civil, criminal, or ad-  
23          ministrative proceeding; or

24           “(5) utilized in a disciplinary proceeding  
25          against a provider.

1       “(b) CONFIDENTIALITY.—Notwithstanding any other  
2 provision of Federal, State, or local law, and subject to  
3 the provisions of subsections (c) and (d), patient safety  
4 data shall be confidential and shall not be disclosed.

5       “(c) EXCEPTIONS TO PRIVILEGE AND CONFIDEN-  
6 TIALITY.—Nothing in this section shall be construed to  
7 prohibit one or more of the following uses or disclosures:

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

14           “(2) Voluntary disclosure of non-identifiable pa-  
15 tient safety data by a provider or a patient safety  
16 organization.

17       “(d) PROTECTED DISCLOSURE AND USE OF INFOR-  
18 MATION.—Nothing in this section shall be construed to  
19 prohibit one or more of the following uses or disclosures:

20           “(1) Disclosure of patient safety data by a per-  
21 son that is a provider, a patient safety organization,  
22 or a contractor of a provider or patient safety orga-  
23 nization, to another such person, to carry out pa-  
24 tient safety organization activities.

1           “(2) Disclosure of patient safety data by a pro-  
2           vider or patient safety organization to grantees or  
3           contractors carrying out patient safety research,  
4           evaluation, or demonstration projects authorized by  
5           the Director.

6           “(3) Disclosure of patient safety data by a pro-  
7           vider to an accrediting body that accredits that pro-  
8           vider.

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

1           “(5) Voluntary disclosure of patient safety data  
2           by a patient safety organization to State of local  
3           government agencies for public health surveillance if  
4           the consent of each provider identified in, or pro-  
5           viding, such data is obtained prior to such disclo-  
6           sure. Nothing in the preceding sentence shall be con-  
7           strued to prevent the release of patient safety data  
8           that is provided by, or that relates solely to, a pro-  
9           vider from which the consent described in such sen-  
10          tence is obtained because one or more other pro-  
11          viders do not provide such consent with respect to  
12          the disclosure of patient safety data that relates to  
13          such nonconsenting providers. Consent for the fu-  
14          ture release of patient safety data for such purposes  
15          may be requested by the patient safety organization  
16          at the time the data is submitted.

17          “(e) CONTINUED PROTECTION OF INFORMATION  
18 AFTER DISCLOSURE.—

19           “(1) IN GENERAL.—Except as provided in para-  
20           graph (2), patient safety data that is used or dis-  
21           closed shall continue to be privileged and confiden-  
22           tial as provided for in subsections (a) and (b), and  
23           the provisions of such subsections shall apply to  
24           such data in the possession or control of—

1           “(A) a provider or patient safety organiza-  
2           tion that possessed such data before the use or  
3           disclosure; or

4           “(B) a person to whom such data was dis-  
5           closed.

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

8           “(A) if patient safety data is used or dis-  
9           closed as provided for in subsection (c)(1), and  
10          such use or disclosure is in open court, the con-  
11          fidentiality protections provided for in sub-  
12          section (b) shall no longer apply to such data;  
13          and

14          “(B) if patient safety data is used or dis-  
15          closed as provided for in subsection (c)(2), the  
16          privilege and confidentiality protections pro-  
17          vided for in subsections (a) and (b) shall no  
18          longer apply to such data.

19          “(3) CONSTRUCTION.—Paragraph (2) shall not  
20          be construed as terminating or limiting the privilege  
21          or confidentiality protections provided for in sub-  
22          section (a) or (b) with respect to data other than the  
23          specific data used or disclosed as provided for in  
24          subsection (c).

25          “(f) LIMITATION ON ACTIONS.—

1           “(1) PATIENT SAFETY ORGANIZATIONS.—Ex-  
2           cept to enforce disclosures pursuant to subsection  
3           (c)(1), no action may be brought or process served  
4           against a patient safety organization to compel dis-  
5           closure of information collected or developed under  
6           this part whether or not such information is patient  
7           safety data unless such information is specifically  
8           identified, is not patient safety data, and cannot oth-  
9           erwise be obtained.

10           “(2) PROVIDERS.—An accrediting body shall  
11           not take an accrediting action against a provider  
12           based on the good faith participation of the provider  
13           in the collection, development, reporting, or mainte-  
14           nance of patient safety data in accordance with this  
15           part. An accrediting body may not require a provider  
16           to reveal its communications with any patient safety  
17           organization established in accordance with this  
18           part.

19           “(g) REPORTER PROTECTION.—

20           “(1) IN GENERAL.—A provider may not take an  
21           adverse employment action, as described in para-  
22           graph (2), against an individual based upon the fact  
23           that the individual in good faith reported informa-  
24           tion—



1           “(A) to the provider with the intention of  
2           having the information reported to a patient  
3           safety organization; or

4           “(B) directly to a patient safety organiza-  
5           tion.

6           “(2) ADVERSE EMPLOYMENT ACTION.—For  
7           purposes of this subsection, an ‘adverse employment  
8           action’ includes—

9           “(A) loss of employment, the failure to  
10          promote an individual, or the failure to provide  
11          any other employment-related benefit for which  
12          the individual would otherwise be eligible; or

13          “(B) an adverse evaluation or decision  
14          made in relation to accreditation, certification,  
15          credentialing, or licensing of the individual.

16          “(h) ENFORCEMENT.—

17          “(1) PROHIBITION.—Except as provided in sub-  
18          sections (c) and (d) and as otherwise provided for in  
19          this section, it shall be unlawful for any person to  
20          negligently or intentionally disclose any patient safe-  
21          ty data, and any such person shall, upon adjudica-  
22          tion, be assessed in accordance with section 934(d).

23          “(2) RELATION TO HIPAA.—The penalty pro-  
24          vided for under paragraph (1) shall not apply if the  
25          defendant would otherwise be subject to a penalty

1 under the regulations promulgated under section  
2 264(c) of the Health Insurance Portability and Ac-  
3 countability Act of 1996 (42 U.S.C. 1320d-2 note)  
4 or under section 1176 of the Social Security Act (42  
5 U.S.C. 1320d-5) for the same disclosure.

6 “(3) **EQUITABLE RELIEF.**—

7 “(A) **IN GENERAL.**—Without limiting rem-  
8 edies available to other parties, a civil action  
9 may be brought by any aggrieved individual to  
10 enjoin any act or practice that violates sub-  
11 section (g) and to obtain other appropriate eq-  
12 uitable relief (including reinstatement, back  
13 pay, and restoration of benefits) to redress such  
14 violation.

15 “(B) **AGAINST STATE EMPLOYEES.**—An  
16 entity that is a State or an agency of a State  
17 government may not assert the privilege de-  
18 scribed in subsection (a) unless before the time  
19 of the assertion, the entity or, in the case of  
20 and with respect to an agency, the State has  
21 consented to be subject to an action as de-  
22 scribed by this paragraph, and that consent has  
23 remained in effect.

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

1           “(1) limit other privileges that are available  
2           under Federal, State, or local laws that provide  
3           greater confidentiality protections or privileges than  
4           the privilege and confidentiality protections provided  
5           for in this section;

6           “(2) limit, alter, or affect the requirements of  
7           Federal, State, or local law pertaining to informa-  
8           tion that is not privileged or confidential under this  
9           section;

10           “(3) alter or affect the implementation of any  
11           provision of section 264(c) of the Health Insurance  
12           Portability and Accountability Act of 1996 (Public  
13           Law 104–191; 110 Stat. 2033), section 1176 of the  
14           Social Security Act (42 U.S.C. 1320d–5), or any  
15           regulation promulgated under such sections;

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

21           “(5) prohibit a provider from reporting a crime  
22           to law enforcement authorities, regardless of whether  
23           knowledge of the existence of, or the description of,  
24           the crime is based on patient safety data, so long as

1 the provider does not disclose patient safety data in  
2 making such report.

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

4 “(a) IN GENERAL.—The Secretary shall maintain a  
5 patient safety network of databases that provides an inter-  
6 active evidence-based management resource for providers,  
7 patient safety organizations, and other persons. The net-  
8 work of databases shall have the capacity to accept, aggre-  
9 gate, and analyze nonidentifiable patient safety data vol-  
10 untarily reported by patient safety organizations, pro-  
11 viders, or other persons.

12 “(b) NETWORK OF DATABASE STANDARDS.—The  
13 Secretary may determine common formats for the report-  
14 ing to the patient safety network of databases maintained  
15 under subsection (a) of nonidentifiable patient safety data,  
16 including necessary data elements, common and consistent  
17 definitions, and a standardized computer interface for the  
18 processing of such data. To the extent practicable, such  
19 standards shall be consistent with the administrative sim-  
20 plification provisions of Part C of title XI of the Social  
21 Security Act.

22 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-  
23 CATION AND LISTING.**

24 “(a) CERTIFICATION.—

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

6           “(2) DELAYED CERTIFICATION OF COLLECTION  
7           FROM MORE THAN ONE PROVIDER.—An entity that  
8           seeks to be a patient safety organization may—

9           “(A) submit an initial certification that it  
10           intends to perform patient safety organization  
11           activities other than the activities described in  
12           subparagraph (B) of section 921(4); and

13           “(B) within 2 years of submitting the ini-  
14           tial certification under subparagraph (A), sub-  
15           mit a supplemental certification that it per-  
16           forms the patient safety organization activities  
17           described in subparagraphs (A) through (F) of  
18           section 921(4).

19           “(3) EXPIRATION AND RENEWAL.—

20           “(A) EXPIRATION.—An initial certification  
21           under paragraph (1) or (2)(A) shall expire on  
22           the date that is 3 years after it is submitted.

23           “(B) RENEWAL.—

24           “(i) IN GENERAL.—An entity that  
25           seeks to remain a patient safety organiza-

1           tion after the expiration of an initial cer-  
2           tification under paragraph (1) or (2)(A)  
3           shall, within the 3-year period described in  
4           subparagraph (A), submit a renewal cer-  
5           tification to the Secretary that the entity  
6           performs the patient safety organization  
7           activities described in section 921(4).

8           “(ii) TERM OF RENEWAL.—A renewal  
9           certification under clause (i) shall expire  
10          on the date that is 3 years after the date  
11          on which it is submitted, and may be re-  
12          newed in the same manner as an initial  
13          certification.

14          “(b) ACCEPTANCE OF CERTIFICATION.—Upon the  
15          submission by an organization of an initial certification  
16          pursuant to subsection (a)(1) or (a)(2)(A), a supplemental  
17          certification pursuant to subsection (a)(2)(B), or a re-  
18          newal certification pursuant to subsection (a)(3)(B), the  
19          Secretary shall review such certification and—

20                 “(1) if such certification meets the require-  
21                 ments of subsection (a)(1), (a)(2)(A), (a)(2)(B), or  
22                 (a)(3)(B), as applicable, the Secretary shall notify  
23                 the organization that such certification is accepted;  
24                 or

1           “(2) if such certification does not meet such re-  
2           quirements, as applicable, the Secretary shall notify  
3           the organization that such certification is not accept-  
4           ed and the reasons therefor.

5           “(c) LISTING.—

6           “(1) IN GENERAL.—Except as otherwise pro-  
7           vided in this subsection, the Secretary shall compile  
8           and maintain a current listing of patient safety or-  
9           ganizations with respect to which the Secretary has  
10          accepted a certification pursuant to subsection (b).

11          “(2) REMOVAL FROM LISTING.—The Secretary  
12          shall remove from the listing under paragraph (1)—

13                 “(A) an entity with respect to which the  
14                 Secretary has accepted an initial certification  
15                 pursuant to subsection (a)(2)(A) and which  
16                 does not submit a supplemental certification  
17                 pursuant to subsection (a)(2)(B) that is accept-  
18                 ed by the Secretary;

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

22                 “(C) an entity with respect to which the  
23                 Secretary revokes the Secretary’s acceptance of  
24                 the entity’s certification, pursuant to subsection  
25                 (d).

1 “(d) REVOCATION OF ACCEPTANCE.—

2 “(1) IN GENERAL.—Except as provided in para-  
3 graph (2), if the Secretary determines (through a re-  
4 view of patient safety organization activities) that a  
5 patient safety organization does not perform one of  
6 the patient safety organization activities described in  
7 subparagraph (A) through (F) of section 921(4), the  
8 Secretary may, after notice and an opportunity for  
9 a hearing, revoke the Secretary’s acceptance of the  
10 certification of such organization.

11 “(2) DELAYED CERTIFICATION OF COLLECTION  
12 FROM MORE THAN ONE PROVIDER.—A revocation  
13 under paragraph (1) may not be based on a deter-  
14 mination that the organization does not perform the  
15 activity described in section 921(4)(B) if—

16 “(A) the listing of the organization is  
17 based on its submittal of an initial certification  
18 under subsection (a)(2)(A);

19 “(B) the organization has not submitted a  
20 supplemental certification under subsection  
21 (a)(2)(B); and

22 “(C) the 2-year period described in sub-  
23 section (a)(2)(B) has not expired.

24 “(e) NOTIFICATION OF REVOCATION OR REMOVAL  
25 FROM LISTING.—



1           “(1) SUPPLYING CONFIRMATION OF NOTIFICA-  
2           TION TO PROVIDERS.—Within 15 days of a revoca-  
3           tion under subsection (d)(1), a patient safety organi-  
4           zation shall submit to the Secretary a confirmation  
5           that the organization has taken all reasonable ac-  
6           tions to notify each provider whose patient safety  
7           data is collected or analyzed by the organization of  
8           such revocation.

9           “(2) PUBLICATION.—Upon the revocation of an  
10          acceptance of an organization’s certification under  
11          subsection (d)(1), or upon the removal of an organi-  
12          zation from the listing under subsection (c)(2), the  
13          Secretary shall publish notice of the revocation or  
14          removal in the Federal Register.

15          “(f) STATUS OF DATA AFTER REMOVAL FROM LIST-  
16          ING.—

17               “(1) NEW DATA.—With respect to the privilege  
18               and confidentiality protections described in section  
19               922, data submitted to an organization within 30  
20               days after the organization is removed from the list-  
21               ing under subsection (c)(2) shall have the same sta-  
22               tus as data submitted while the organization was  
23               still listed.

24               “(2) PROTECTION TO CONTINUE TO APPLY.—If  
25               the privilege and confidentiality protections de-

1 scribed in section 922 applied to data while an orga-  
2 nization was listed, or during the 30-day period de-  
3 scribed in paragraph (1), such protections shall con-  
4 tinue to apply to such data after the organization is  
5 removed from the listing under subsection (c)(2).

6 “(g) DISPOSITION OF DATA.—If the Secretary re-  
7 moves an organization from the listing as provided for in  
8 subsection (c)(2), with respect to the patient safety data  
9 that the organization received from providers, the organi-  
10 zation shall—

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

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

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

18 **“SEC. 925. TECHNICAL ASSISTANCE.**

19 “The Secretary, acting through the Director, may  
20 provide technical assistance to patient safety organiza-  
21 tions, including convening annual meetings for patient  
22 safety organizations to discuss methodology, communica-  
23 tion, data collection, or privacy concerns.

1 **“SEC. 926. PROMOTING THE INTEROPERABILITY OF**  
2 **HEALTH CARE INFORMATION TECHNOLOGY**  
3 **SYSTEMS.**

4 “(a) DEVELOPMENT.—Not later than 36 months  
5 after the date of enactment of the Patient Safety and  
6 Quality Improvement Act of 2005, the Secretary shall de-  
7 velop or adopt voluntary standards that promote the elec-  
8 tronic exchange of health care information.

9 “(b) UPDATES.—The Secretary shall provide for the  
10 ongoing review and periodic updating of the standards de-  
11 veloped under subsection (a).

12 “(c) DISSEMINATION.—The Secretary shall provide  
13 for the dissemination of the standards developed and up-  
14 dated under this section.

15 **“SEC. 927. AUTHORIZATION OF APPROPRIATIONS.**

16 “There is authorized to be appropriated such sums  
17 as may be necessary to carry out this part.”

18 **SEC. 4. STUDIES AND REPORTS.**

19 (a) IN GENERAL.—The Secretary of Health and  
20 Human Services shall enter into a contract (based upon  
21 a competitive contracting process) with an appropriate re-  
22 search organization for the conduct of a study to assess  
23 the impact of medical technologies and therapies on pa-  
24 tient safety, patient benefit, health care quality, and the  
25 costs of care as well as productivity growth. Such study  
26 shall examine—

1           (1) the extent to which factors, such as the use  
2 of labor and technological advances, have contrib-  
3 uted to increases in the share of the gross domestic  
4 product that is devoted to health care and the im-  
5 pact of medical technologies and therapies on such  
6 increases;

7           (2) the extent to which early and appropriate  
8 introduction and integration of innovative medical  
9 technologies and therapies may affect the overall  
10 productivity and quality of the health care delivery  
11 systems of the United States; and

12           (3) the relationship of such medical technologies  
13 and therapies to patient safety, patient benefit,  
14 health care quality, and cost of care.

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

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