

109TH CONGRESS
1ST SESSION

S. 544

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 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Patient Safety and Quality Improvement Act of 2005”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 this Act is as follows:

Sec. 1. Short title; table of contents.
 Sec. 2. Amendments to Public Health Service Act.

“PART C—PATIENT SAFETY IMPROVEMENT

“Sec. 921. Definitions.
 “Sec. 922. Privilege and confidentiality protections.
 “Sec. 923. Network of patient safety databases.
 “Sec. 924. Patient safety organization certification and listing.
 “Sec. 925. Technical assistance.
 “Sec. 926. Severability.

3 **SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

4 (a) IN GENERAL.—Title IX of the Public Health
 5 Service Act (42 U.S.C. 299 et seq.) is amended—

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

8 (2) by redesignating part C as part D;

9 (3) by redesignating sections 921 through 928,
 10 as sections 931 through 938, respectively;

11 (4) in section 938(1) (as so redesignated), by
 12 striking “921” and inserting “931”; and

13 (5) by inserting after part B the following:

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

15 **“SEC. 921. DEFINITIONS.**

16 “In this part:

17 “(1) HIPAA CONFIDENTIALITY REGULA-
 18 TIONS.—The term ‘HIPAA confidentiality regula-
 19 tions’ means regulations promulgated under section
 20 264(c) of the Health Insurance Portability and Ac-

1 countability Act of 1996 (Public Law 104–191; 110
2 Stat. 2033).

3 “(2) IDENTIFIABLE PATIENT SAFETY WORK
4 PRODUCT.—The term ‘identifiable patient safety
5 work product’ means patient safety work product
6 that—

7 “(A) is presented in a form and manner
8 that allows the identification of any provider
9 that is a subject of the work product, or any
10 providers that participate in activities that are
11 a subject of the work product;

12 “(B) constitutes individually identifiable
13 health information as that term is defined in
14 the HIPAA confidentiality regulations; or

15 “(C) is presented in a form and manner
16 that allows the identification of an individual
17 who reported information in the manner speci-
18 fied in section 922(e).

19 “(3) NONIDENTIFIABLE PATIENT SAFETY WORK
20 PRODUCT.—The term ‘nonidentifiable patient safety
21 work product’ means patient safety work product
22 that is not identifiable patient safety work product
23 (as defined in paragraph (2)).

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

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

3 “(5) PATIENT SAFETY ACTIVITIES.—The term
4 ‘patient safety activities’ means the following activi-
5 ties:

6 “(A) Efforts to improve patient safety and
7 the quality of health care delivery.

8 “(B) The collection and analysis of patient
9 safety work product.

10 “(C) The development and dissemination
11 of information with respect to improving patient
12 safety, such as recommendations, protocols, or
13 information regarding best practices.

14 “(D) The utilization of patient safety work
15 product for the purposes of encouraging a cul-
16 ture of safety and of providing feedback and as-
17 sistance to effectively minimize patient risk.

18 “(E) The maintenance of procedures to
19 preserve confidentiality with respect to patient
20 safety work product.

21 “(F) The provision of appropriate security
22 measures with respect to patient safety work
23 product.

24 “(G) The utilization of qualified staff.

1 “(H) Activities related to the operation of
2 a patient safety evaluation system and to the
3 provision of feedback to participants in a pa-
4 tient safety evaluation system.

5 “(6) PATIENT SAFETY EVALUATION SYSTEM.—
6 The term ‘patient safety evaluation system’ means
7 the collection, management, or analysis of informa-
8 tion for reporting to or by a patient safety organiza-
9 tion.

10 “(7) PATIENT SAFETY WORK PRODUCT.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B), the term ‘patient safety
13 work product’ means any data, reports, records,
14 memoranda, analyses (such as root cause anal-
15 yses), or written or oral statements—

16 “(i) which—

17 “(I) are assembled or developed
18 by a provider for reporting to a pa-
19 tient safety organization and are re-
20 ported to a patient safety organiza-
21 tion; or

22 “(II) are developed by a patient
23 safety organization for the conduct of
24 patient safety activities;

1 and which could result in improved patient
2 safety, health care quality, or health care
3 outcomes; or

4 “(ii) which identify or constitute the
5 deliberations or analysis of, or identify the
6 fact of reporting pursuant to, a patient
7 safety evaluation system.

8 “(B) CLARIFICATION.—

9 “(i) Information described in subpara-
10 graph (A) does not include a patient’s
11 medical record, billing and discharge infor-
12 mation, or any other original patient or
13 provider record.

14 “(ii) Information described in sub-
15 paragraph (A) does not include informa-
16 tion that is collected, maintained, or devel-
17 oped separately, or exists separately, from
18 a patient safety evaluation system. Such
19 separate information or a copy thereof re-
20 ported to a patient safety organization
21 shall not by reason of its reporting be con-
22 sidered patient safety work product.

23 “(iii) Nothing in this part shall be
24 construed to limit—

1 “(I) the discovery of or admissi-
2 bility of information described in this
3 subparagraph in a criminal, civil, or
4 administrative proceeding;

5 “(II) the reporting of information
6 described in this subparagraph to a
7 Federal, State, or local governmental
8 agency for public health surveillance,
9 investigation, or other public health
10 purposes or health oversight purposes;
11 or

12 “(III) a provider’s recordkeeping
13 obligation with respect to information
14 described in this subparagraph under
15 Federal, State, or local law.

16 “(8) PROVIDER.—The term ‘provider’ means—

17 “(A) an individual or entity licensed or
18 otherwise authorized under State law to provide
19 health care services, including—

20 “(i) a hospital, nursing facility, com-
21 prehensive outpatient rehabilitation facil-
22 ity, home health agency, hospice program,
23 renal dialysis facility, ambulatory surgical
24 center, pharmacy, physician or health care
25 practitioner’s office, long term care facility,

1 behavior health residential treatment facil-
2 ity, clinical laboratory, or health center; or
3 “(ii) a physician, physician assistant,
4 nurse practitioner, clinical nurse specialist,
5 certified registered nurse anesthetist, cer-
6 tified nurse midwife, psychologist, certified
7 social worker, registered dietitian or nutri-
8 tion professional, physical or occupational
9 therapist, pharmacist, or other individual
10 health care practitioner; or
11 “(B) any other individual or entity speci-
12 fied in regulations promulgated by the Sec-
13 retary.

14 **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**
15 **TIONS.**

16 “(a) PRIVILEGE.—Notwithstanding any other provi-
17 sion of Federal, State, or local law, and subject to sub-
18 section (c), patient safety work product shall be privileged
19 and shall not be—

20 “(1) subject to a Federal, State, or local civil,
21 criminal, or administrative subpoena or order, in-
22 cluding in a Federal, State, or local civil or adminis-
23 trative disciplinary proceeding against a provider;

24 “(2) subject to discovery in connection with a
25 Federal, State, or local civil, criminal, or administra-

1 tive proceeding, including in a Federal, State, or
2 local civil or administrative disciplinary proceeding
3 against a provider;

4 “(3) subject to disclosure pursuant to section
5 552 of title 5, United States Code (commonly known
6 as the Freedom of Information Act) or any other
7 similar Federal, State, or local law;

8 “(4) admitted as evidence in any Federal,
9 State, or local governmental civil proceeding, crimi-
10 nal proceeding, administrative rulemaking pro-
11 ceeding, or administrative adjudicatory proceeding,
12 including any such proceeding against a provider; or

13 “(5) admitted in a professional disciplinary pro-
14 ceeding of a professional disciplinary body estab-
15 lished or specifically authorized under State law.

16 “(b) CONFIDENTIALITY OF PATIENT SAFETY WORK
17 PRODUCT.—Notwithstanding any other provision of Fed-
18 eral, State, or local law, and subject to subsection (c), pa-
19 tient safety work product shall be confidential and shall
20 not be disclosed.

21 “(c) EXCEPTIONS.—Except as provided in subsection
22 (g)(3)—

23 “(1) EXCEPTIONS FROM PRIVILEGE AND CON-
24 FIDENTIALITY.—Subsections (a) and (b) shall not

1 apply to (and shall not be construed to prohibit) one
2 or more of the following disclosures:

3 “(A) Disclosure of relevant patient safety
4 work product for use in a criminal proceeding,
5 but only after a court makes an in camera de-
6 termination that such patient safety work prod-
7 uct contains evidence of a criminal act and that
8 such patient safety work product is material to
9 the proceeding and not reasonably available
10 from any other source.

11 “(B) Disclosure of patient safety work
12 product to the extent required to carry out sub-
13 section (f)(4)(A).

14 “(C) Disclosure of identifiable patient safe-
15 ty work product if authorized by each provider
16 identified in such work product.

17 “(2) EXCEPTIONS FROM CONFIDENTIALITY.—
18 Subsection (b) shall not apply to (and shall not be
19 construed to prohibit) one or more of the following
20 disclosures:

21 “(A) Disclosure of patient safety work
22 product to carry out patient safety activities.

23 “(B) Disclosure of nonidentifiable patient
24 safety work product.

1 “(C) Disclosure of patient safety work
2 product to grantees, contractors, or other enti-
3 ties carrying out research, evaluation, or dem-
4 onstration projects authorized, funded, certified,
5 or otherwise sanctioned by rule or other means
6 by the Secretary, for the purpose of conducting
7 research to the extent that disclosure of pro-
8 tected health information would be allowed for
9 such purpose under the HIPAA confidentiality
10 regulations.

11 “(D) Disclosure by a provider to the Food
12 and Drug Administration with respect to a
13 product or activity regulated by the Food and
14 Drug Administration.

15 “(E) Voluntary disclosure of patient safety
16 work product by a provider to an accrediting
17 body that accredits that provider.

18 “(F) Disclosures that the Secretary may
19 determine, by rule or other means, are nec-
20 essary for business operations and are con-
21 sistent with the goals of this part.

22 “(G) Disclosure of patient safety work
23 product to law enforcement authorities relating
24 to the commission of a crime (or to an event
25 reasonably believed to be a crime) if the person

1 making the disclosure believes, reasonably
2 under the circumstances, that the patient safety
3 work product that is disclosed is necessary for
4 criminal law enforcement purposes.

5 “(H) With respect to a person other than
6 a patient safety organization, the disclosure of
7 patient safety work product that does not in-
8 clude materials that—

9 “(i) assess the quality of care of an
10 identifiable provider; or

11 “(ii) describe or pertain to one or
12 more actions or failures to act by an iden-
13 tifiable provider.

14 “(3) EXCEPTION FROM PRIVILEGE.—Subsection
15 (a) shall not apply to (and shall not be construed to
16 prohibit) voluntary disclosure of nonidentifiable pa-
17 tient safety work product.

18 “(d) CONTINUED PROTECTION OF INFORMATION
19 AFTER DISCLOSURE.—

20 “(1) IN GENERAL.—Patient safety work prod-
21 uct that is disclosed under subsection (c) shall con-
22 tinue to be privileged and confidential as provided
23 for in subsections (a) and (b), and such disclosure
24 shall not be treated as a waiver of privilege or con-
25 fidentiality, and the privileged and confidential na-

1 ture of such work product shall also apply to such
2 work product in the possession or control of a per-
3 son to whom such work product was disclosed.

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

6 “(A) if patient safety work product is dis-
7 closed in a criminal proceeding, the confiden-
8 tiality protections provided for in subsection (b)
9 shall no longer apply to the work product so
10 disclosed; and

11 “(B) if patient safety work product is dis-
12 closed as provided for in subsection (c)(2)(B)
13 (relating to disclosure of nonidentifiable patient
14 safety work product), the privilege and con-
15 fidentiality protections provided for in sub-
16 sections (a) and (b) shall no longer apply to
17 such work product.

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

24 “(4) LIMITATIONS ON ACTIONS.—

25 “(A) PATIENT SAFETY ORGANIZATIONS.—

1 “(i) IN GENERAL.—A patient safety
2 organization shall not be compelled to dis-
3 close information collected or developed
4 under this part whether or not such infor-
5 mation is patient safety work product un-
6 less such information is identified, is not
7 patient safety work product, and is not
8 reasonably available from another source.

9 “(ii) NONAPPLICATION.—The limita-
10 tion contained in clause (i) shall not apply
11 in an action against a patient safety orga-
12 nization or with respect to disclosures pur-
13 suant to subsection (c)(1).

14 “(B) PROVIDERS.—An accrediting body shall
15 not take an accrediting action against a provider
16 based on the good faith participation of the provider
17 in the collection, development, reporting, or mainte-
18 nance of patient safety work product in accordance
19 with this part. An accrediting body may not require
20 a provider to reveal its communications with any pa-
21 tient safety organization established in accordance
22 with this part.

23 “(e) REPORTER PROTECTION.—

24 “(1) IN GENERAL.—A provider may not take an
25 adverse employment action, as described in para-

1 graph (2), against an individual based upon the fact
2 that the individual in good faith reported
3 information—

4 “(A) to the provider with the intention of
5 having the information reported to a patient
6 safety organization; or

7 “(B) directly to a patient safety organiza-
8 tion.

9 “(2) ADVERSE EMPLOYMENT ACTION.—For
10 purposes of this subsection, an ‘adverse employment
11 action’ includes—

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

16 “(B) an adverse evaluation or decision
17 made in relation to accreditation, certification,
18 credentialing, or licensing of the individual.

19 “(f) ENFORCEMENT.—

20 “(1) CIVIL MONETARY PENALTY.—Subject to
21 paragraphs (2) and (3), a person who discloses iden-
22 tifiable patient safety work product in knowing or
23 reckless violation of subsection (b) shall be subject
24 to a civil monetary penalty of not more than
25 \$10,000 for each act constituting such violation.

1 “(2) PROCEDURE.—The provisions of section
2 1128A of the Social Security Act, other than sub-
3 sections (a) and (b) and the first sentence of sub-
4 section (c)(1), shall apply to civil money penalties
5 under this subsection in the same manner as such
6 provisions apply to a penalty or proceeding under
7 section 1128A of the Social Security Act.

8 “(3) RELATION TO HIPAA.—Penalties shall not
9 be imposed both under this subsection and under the
10 regulations issued pursuant to section 264(e)(1) of
11 the Health Insurance Portability and Accountability
12 Act of 1996 (42 U.S.C. 1320d-2 note) for a single
13 act or omission.

14 “(4) EQUITABLE RELIEF.—

15 “(A) IN GENERAL.—Without limiting rem-
16 edies available to other parties, a civil action
17 may be brought by any aggrieved individual to
18 enjoin any act or practice that violates sub-
19 section (e) and to obtain other appropriate eq-
20 uitable relief (including reinstatement, back
21 pay, and restoration of benefits) to redress such
22 violation.

23 “(B) AGAINST STATE EMPLOYEES.—An
24 entity that is a State or an agency of a State
25 government may not assert the privilege de-

1 scribed in subsection (a) unless before the time
2 of the assertion, the entity or, in the case of
3 and with respect to an agency, the State has
4 consented to be subject to an action described
5 in subparagraph (A), and that consent has re-
6 mained in effect.

7 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed—

9 “(1) to limit the application of other Federal,
10 State, or local laws that provide greater privilege or
11 confidentiality protections than the privilege and
12 confidentiality protections provided for in this sec-
13 tion;

14 “(2) to limit, alter, or affect the requirements
15 of Federal, State, or local law pertaining to informa-
16 tion that is not privileged or confidential under this
17 section;

18 “(3) except as provided in subsection (i), to
19 alter or affect the implementation of any provision
20 of the HIPAA confidentiality regulations or section
21 1176 of the Social Security Act (or regulations pro-
22 mulgated under such section);

23 “(4) to limit the authority of any provider, pa-
24 tient safety organization, or other entity to enter
25 into a contract requiring greater confidentiality or

1 delegating authority to make a disclosure or use in
2 accordance with this section;

3 “(5) as preempting or otherwise affecting any
4 State law requiring a provider to report information
5 that is not patient safety work product; or

6 “(6) to limit, alter, or affect any requirement
7 for reporting to the Food and Drug Administration
8 information regarding the safety of a product or ac-
9 tivity regulated by the Food and Drug Administra-
10 tion.

11 “(h) CLARIFICATION.—Nothing in this part prohibits
12 any person from conducting additional analysis for any
13 purpose regardless of whether such additional analysis in-
14 volves issues identical to or similar to those for which in-
15 formation was reported to or assessed by a patient safety
16 organization or a patient safety evaluation system.

17 “(i) CLARIFICATION OF APPLICATION OF HIPAA CON-
18 FIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGA-
19 NIZATIONS.—For purposes of applying the HIPAA con-
20 fidentiality regulations—

21 “(1) patient safety organizations shall be treat-
22 ed as business associates; and

23 “(2) patient safety activities of such organiza-
24 tions in relation to a provider are deemed to be

1 health care operations (as defined in such regula-
2 tions) of the provider.

3 “(j) REPORTS ON STRATEGIES TO IMPROVE PATIENT
4 SAFETY.—

5 “(1) DRAFT REPORT.—Not later than the date
6 that is 18 months after any network of patient safe-
7 ty databases is operational, the Secretary, in con-
8 sultation with the Director, shall prepare a draft re-
9 port on effective strategies for reducing medical er-
10 rors and increasing patient safety. The draft report
11 shall include any measure determined appropriate by
12 the Secretary to encourage the appropriate use of
13 such strategies, including use in any federally fund-
14 ed programs. The Secretary shall make the draft re-
15 port available for public comment and submit the
16 draft report to the Institute of Medicine for review.

17 “(2) FINAL REPORT.—Not later than 1 year
18 after the date described in paragraph (1), the Sec-
19 retary shall submit a final report to the Congress.

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

21 “(a) IN GENERAL.—The Secretary shall facilitate the
22 creation of, and maintain, a network of patient safety
23 databases that provides an interactive evidence-based
24 management resource for providers, patient safety organi-
25 zations, and other entities. The network of databases shall

1 have the capacity to accept, aggregate across the network,
2 and analyze nonidentifiable patient safety work product
3 voluntarily reported by patient safety organizations, pro-
4 viders, or other entities. The Secretary shall assess the
5 feasibility of providing for a single point of access to the
6 network for qualified researchers for information aggre-
7 gated across the network and, if feasible, provide for im-
8 plementation.

9 “(b) DATA STANDARDS.—The Secretary may deter-
10 mine common formats for the reporting to and among the
11 network of patient safety databases maintained under sub-
12 section (a) of nonidentifiable patient safety work product,
13 including necessary work product elements, common and
14 consistent definitions, and a standardized computer inter-
15 face for the processing of such work product. To the ex-
16 tent practicable, such standards shall be consistent with
17 the administrative simplification provisions of part C of
18 title XI of the Social Security Act.

19 “(c) USE OF INFORMATION.—Information reported
20 to and among the network of patient safety databases
21 under subsection (a) shall be used to analyze national and
22 regional statistics, including trends and patterns of health
23 care errors. The information resulting from such analyses
24 shall be made available to the public and included in the
25 annual quality reports prepared under section 913(b)(2).

1 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**
2 **CATION AND LISTING.**

3 “(a) CERTIFICATION.—

4 “(1) INITIAL CERTIFICATION.—An entity that
5 seeks to be a patient safety organization shall sub-
6 mit an initial certification to the Secretary that the
7 entity—

8 “(A) has policies and procedures in place
9 to perform each of the patient safety activities
10 described in section 921(5); and

11 “(B) upon being listed under subsection
12 (d), will comply with the criteria described in
13 subsection (b).

14 “(2) SUBSEQUENT CERTIFICATIONS.—An entity
15 that is a patient safety organization shall submit
16 every 3 years after the date of its initial listing
17 under subsection (d) a subsequent certification to
18 the Secretary that the entity—

19 “(A) is performing each of the patient
20 safety activities described in section 921(5); and

21 “(B) is complying with the criteria de-
22 scribed in subsection (b).

23 “(b) CRITERIA.—

24 “(1) IN GENERAL.—The following are criteria
25 for the initial and subsequent certification of an en-
26 tity as a patient safety organization:

1 “(A) The mission and primary activity of
2 the entity are to conduct activities that are to
3 improve patient safety and the quality of health
4 care delivery.

5 “(B) The entity has appropriately qualified
6 staff (whether directly or through contract), in-
7 cluding licensed or certified medical profes-
8 sionals.

9 “(C) The entity, within each 24-month pe-
10 riod that begins after the date of the initial list-
11 ing under subsection (d), has bona fide con-
12 tracts, each of a reasonable period of time, with
13 more than 1 provider for the purpose of receiv-
14 ing and reviewing patient safety work product.

15 “(D) The entity is not, and is not a com-
16 ponent of, a health insurance issuer (as defined
17 in section 2791(b)(2)).

18 “(E) The entity shall fully disclose—

19 “(i) any financial, reporting, or con-
20 tractual relationship between the entity
21 and any provider that contracts with the
22 entity; and

23 “(ii) if applicable, the fact that the
24 entity is not managed, controlled, and op-

1 erated independently from any provider
2 that contracts with the entity.

3 “(F) To the extent practical and appro-
4 priate, the entity collects patient safety work
5 product from providers in a standardized man-
6 ner that permits valid comparisons of similar
7 cases among similar providers.

8 “(G) The utilization of patient safety work
9 product for the purpose of providing direct
10 feedback and assistance to providers to effec-
11 tively minimize patient risk.

12 “(2) ADDITIONAL CRITERIA FOR COMPONENT
13 ORGANIZATIONS.—If an entity that seeks to be a pa-
14 tient safety organization is a component of another
15 organization, the following are additional criteria for
16 the initial and subsequent certification of the entity
17 as a patient safety organization:

18 “(A) The entity maintains patient safety
19 work product separately from the rest of the or-
20 ganization, and establishes appropriate security
21 measures to maintain the confidentiality of the
22 patient safety work product.

23 “(B) The entity does not make an unau-
24 thorized disclosure under this part of patient

1 safety work product to the rest of the organiza-
2 tion in breach of confidentiality.

3 “(C) The mission of the entity does not
4 create a conflict of interest with the rest of the
5 organization.

6 “(c) REVIEW OF CERTIFICATION.—

7 “(1) IN GENERAL.—

8 “(A) INITIAL CERTIFICATION.—Upon the
9 submission by an entity of an initial certifi-
10 cation under subsection (a)(1), the Secretary
11 shall determine if the certification meets the re-
12 quirements of subparagraphs (A) and (B) of
13 such subsection.

14 “(B) SUBSEQUENT CERTIFICATION.—
15 Upon the submission by an entity of a subse-
16 quent certification under subsection (a)(2), the
17 Secretary shall review the certification with re-
18 spect to requirements of subparagraphs (A) and
19 (B) of such subsection.

20 “(2) NOTICE OF ACCEPTANCE OR NON-ACCEPT-
21 ANCE.—If the Secretary determines that—

22 “(A) an entity’s initial certification meets
23 requirements referred to in paragraph (1)(A),
24 the Secretary shall notify the entity of the ac-
25 ceptance of such certification; or

1 “(B) an entity’s initial certification does
2 not meet such requirements, the Secretary shall
3 notify the entity that such certification is not
4 accepted and the reasons therefor.

5 “(3) DISCLOSURES REGARDING RELATIONSHIP
6 TO PROVIDERS.—The Secretary shall consider any
7 disclosures under subsection (b)(1)(E) by an entity
8 and shall make public findings on whether the entity
9 can fairly and accurately perform the patient safety
10 activities of a patient safety organization. The Sec-
11 retary shall take those findings into consideration in
12 determining whether to accept the entity’s initial
13 certification and any subsequent certification sub-
14 mitted under subsection (a) and, based on those
15 findings, may deny, condition, or revoke acceptance
16 of the entity’s certification.

17 “(d) LISTING.—The Secretary shall compile and
18 maintain a listing of entities with respect to which there
19 is an acceptance of a certification pursuant to subsection
20 (c)(2)(A) that has not been revoked under subsection (e)
21 or voluntarily relinquished.

22 “(e) REVOCATION OF ACCEPTANCE OF CERTIFI-
23 CATION.—

24 “(1) IN GENERAL.—If, after notice of defi-
25 ciency, an opportunity for a hearing, and a reason-

1 able opportunity for correction, the Secretary deter-
2 mines that a patient safety organization does not
3 meet the certification requirements under subsection
4 (a)(2), including subparagraphs (A) and (B) of such
5 subsection, the Secretary shall revoke the Sec-
6 retary’s acceptance of the certification of such orga-
7 nization.

8 “(2) SUPPLYING CONFIRMATION OF NOTIFICA-
9 TION TO PROVIDERS.—Within 15 days of a revoca-
10 tion under paragraph (1), a patient safety organiza-
11 tion shall submit to the Secretary a confirmation
12 that the organization has taken all reasonable ac-
13 tions to notify each provider whose patient safety
14 work product is collected or analyzed by the organi-
15 zation of such revocation.

16 “(3) PUBLICATION OF DECISION.—If the Sec-
17 retary revokes the certification of an organization
18 under paragraph (1), the Secretary shall—

19 “(A) remove the organization from the list-
20 ing maintained under subsection (d); and

21 “(B) publish notice of the revocation in the
22 Federal Register.

23 “(f) STATUS OF DATA AFTER REMOVAL FROM LIST-
24 ING.—

1 “(1) NEW DATA.—With respect to the privilege
2 and confidentiality protections described in section
3 922, data submitted to an entity within 30 days
4 after the entity is removed from the listing under
5 subsection (e)(3)(A) shall have the same status as
6 data submitted while the entity was still listed.

7 “(2) PROTECTION TO CONTINUE TO APPLY.—If
8 the privilege and confidentiality protections de-
9 scribed in section 922 applied to patient safety work
10 product while an entity was listed, or to data de-
11 scribed in paragraph (1), such protections shall con-
12 tinue to apply to such work product or data after
13 the entity is removed from the listing under sub-
14 section (e)(3)(A).

15 “(g) DISPOSITION OF WORK PRODUCT AND DATA.—
16 If the Secretary removes a patient safety organization
17 from the listing as provided for in subsection (e)(3)(A),
18 with respect to the patient safety work product or data
19 described in subsection (f)(1) that the patient safety orga-
20 nization received from another entity, such former patient
21 safety organization shall—

22 “(1) with the approval of the other entity and
23 a patient safety organization, transfer such work
24 product or data to such patient safety organization;

1 “(2) return such work product or data to the
2 entity that submitted the work product or data; or

3 “(3) if returning such work product or data to
4 such entity is not practicable, destroy such work
5 product or data.

6 **“SEC. 925. TECHNICAL ASSISTANCE.**

7 “The Secretary, acting through the Director, may
8 provide technical assistance to patient safety organiza-
9 tions, including convening annual meetings for patient
10 safety organizations to discuss methodology, communica-
11 tion, data collection, or privacy concerns.

12 **“SEC. 926. SEVERABILITY.**

13 “If any provision of this part is held to be unconstitu-
14 tional, the remainder of this part shall not be affected.”.

15 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
16 937 of the Public Health Service Act (as redesignated by
17 subsection (a)) is amended by adding at the end the fol-
18 lowing:

19 “(e) PATIENT SAFETY AND QUALITY IMPROVE-
20 MENT.—For the purpose of carrying out part C, there are
21 authorized to be appropriated such sums as may be nec-
22 essary for each of the fiscal years 2006 through 2010.”.

23 (c) GAO STUDY ON IMPLEMENTATION.—

24 (1) STUDY.—The Comptroller General of the
25 United States shall conduct a study on the effective-

1 ness of part C of title IX of the Public Health Serv-
2 ice Act (as added by subsection (a)) in accom-
3 plishing the purposes of such part.

4 (2) REPORT.—Not later than February 1,
5 2010, the Comptroller General shall submit a report
6 on the study conducted under paragraph (1). Such
7 report shall include such recommendations for
8 changes in such part as the Comptroller General
9 deems appropriate.

Passed the Senate July 21, 2005.

Attest:

Secretary.

109TH CONGRESS
1ST SESSION

S. 544

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.