

106TH CONGRESS
1ST SESSION

H. R. 3010

To amend titles XVIII and XIX of the Social Security Act to ensure that individuals enjoy the right to be free from restraint, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 4, 1999

Mr. SHAYS (for himself, Ms. DELAURO, Mr. GEJDENSON, Mr. LARSON, and Mr. MALONEY of Connecticut) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to ensure that individuals enjoy the right to be free from restraint, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Restraint Safety Act
5 of 1999”.

1 **SEC. 2. INDIVIDUALS' RIGHT TO FREEDOM FROM RE-**
2 **STRAINT AND REPORTING OF SENTINEL**
3 **EVENTS UNDER MEDICARE.**

4 (a) AMENDMENT TO SOCIAL SECURITY ACT.—

5 (1) IN GENERAL.—Part D of title XVIII of the
6 Social Security Act (42 U.S.C. 1395x et seq.) is
7 amended by adding at the end the following:

8 “INDIVIDUALS’ FREEDOM FROM RESTRAINT AND
9 REPORTING OF SENTINEL EVENTS

10 “SEC. 1897. (a) DEFINITIONS.—In this section:

11 “(1) CHEMICAL RESTRAINT.—The term ‘chem-
12 ical restraint’ means the non-therapeutic use of a
13 medication that—

14 “(A) is unrelated to the patient’s medical
15 condition; and

16 “(B) is imposed for disciplinary purposes
17 or the convenience of staff.

18 “(2) PHYSICAL RESTRAINT.—The term ‘phys-
19 ical restraint’ means any mechanical or personal re-
20 striction that immobilizes or reduces the ability of
21 an individual to move his or her arms, legs, or head
22 freely. Such term does not include devices, such as
23 orthopedically prescribed devices, surgical dressings
24 or bandages, protective helmets, and other methods
25 involving the physical holding of a resident for the
26 purpose of conducting routine physical examinations

1 or tests or to protect the patient from falling out of
2 bed or to permit a patient to participate in activities
3 without the risk of physical harm to the patient.

4 “(3) PROVIDER OF SERVICES.—The term ‘pro-
5 vider of services’ has the meaning given that term
6 in section 1861(u), except that for purposes of this
7 section the term includes a psychiatric hospital but
8 does not include a home health agency.

9 “(4) SECLUSION.—The term ‘seclusion’ means
10 any separation of the resident from the general pop-
11 ulation of the facility that prevents the resident from
12 returning to such population when he or she desires.

13 “(5) SENTINEL EVENT.—The term ‘sentinel
14 event’ means an unexpected occurrence involving an
15 individual in the care of a provider of services for
16 treatment for a psychiatric or psychological illness
17 that results in death or serious physical or psycho-
18 logical injury that is unrelated to the natural course
19 of the individual’s illness or underlying condition.

20 “(b) PROTECTION OF RIGHT TO BE FREE FROM RE-
21 STRAINTS.—A provider of services eligible to be paid
22 under this title for providing services to an individual enti-
23 tled to benefits under part A or enrolled under part B
24 (including an individual provided with a Medicare+Choice

1 plan offered by a Medicare+Choice organization under
2 part C) shall—

3 “(1) protect and promote the right of each such
4 individual to be free from physical or mental abuse,
5 corporal punishment, and any physical or chemical
6 restraints or involuntary seclusion imposed for pur-
7 poses of discipline or convenience;

8 “(2) impose restraints—

9 “(A) only to ensure the physical safety of
10 the individual or other individuals in the care or
11 custody of the provider, a staff member, or oth-
12 ers; and

13 “(B) only upon the written order of a phy-
14 sician or other licensed independent practitioner
15 permitted by the State and the facility to order
16 such restraint or seclusion that specifies the du-
17 ration and circumstances under which the re-
18 straints are to be used (except in emergency
19 circumstances specified by the Secretary until
20 such an order could reasonably be obtained);
21 and

22 “(3) submit the reports required under sub-
23 section (d).

24 “(c) CONSTRUCTION.—Nothing in this section shall
25 be construed as prohibiting the use of restraints for med-

1 ical immobilization, adaptive support, or medical protec-
2 tion.

3 “(d) REPORTS.—

4 “(1) REPORTS TO AGENCIES OR ENTITIES WITH
5 OVERSIGHT AUTHORITY.—

6 “(A) IN GENERAL.—A provider of services
7 shall report each sentinel event that occurs to
8 an individual while the individual is in the care
9 or custody of the provider to—

10 “(i) in the case of a provider of serv-
11 ices participating in the program estab-
12 lished under this title or the medicaid pro-
13 gram under title XIX as a result of accred-
14 itation by a national accrediting body, the
15 national accrediting body for that provider;
16 and

17 “(ii) in the case of all other providers
18 of services, the Secretary or, upon agree-
19 ment between the Secretary and the rel-
20 evant State, the State agency designated
21 by the Secretary.

22 “(B) INVESTIGATION AND FURTHER RE-
23 PORTING OF SENTINEL EVENTS.—Upon receipt
24 of a report made pursuant to subparagraph

1 (A), the agency or entity with oversight author-
2 ity shall—

3 “(i) ensure that the provider—

4 “(I) conducts an investigation of
5 the sentinel event reported;

6 “(II) determines the root cause
7 or causes of the sentinel event; and

8 “(III) establishes a time-limited
9 plan or strategy, that allows the agen-
10 cy or entity with oversight authority
11 to review and approve the analyses
12 and any corrective actions proposed or
13 made by the provider of services, to
14 correct the problem or problems that
15 resulted in the sentinel event, and to
16 lead to risk reduction; and

17 “(ii) prepare and submit the reports
18 required under paragraph (2).

19 “(2) REPORTS TO THE SECRETARY.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (D), the agency or entity with oversight
22 authority shall submit a report containing the
23 information described in subparagraph (B) to
24 the Secretary in such form and manner, and by
25 such date, as the Secretary prescribes.

1 “(B) INFORMATION TO BE REPORTED.—

2 “(i) IN GENERAL.—The report sub-
3 mitted under subparagraph (A) shall be
4 submitted to the Secretary at regular in-
5 tervals, but not less frequently than annu-
6 ally, and shall include—

7 “(I) a description of the sentinel
8 events occurring during the period
9 covered by the report;

10 “(II) a description of any correc-
11 tive action taken by the providers of
12 services with respect to the sentinel
13 events or any other measures nec-
14 essary to prevent similar sentinel
15 events from occurring in the future;

16 “(III) proposed systems changes
17 identified as a result of analysis of
18 events from multiple providers; and

19 “(IV) such additional information
20 as the Secretary determines to be es-
21 sential to ensure compliance with the
22 requirements of this section.

23 “(ii) INFORMATION EXCLUDED.—The
24 report submitted under subparagraph (A)

1 shall not identify any individual provider of
2 services, practitioner, or individual.

3 “(C) ADDITIONAL REPORTING REQUIRE-
4 MENTS WHEN A PROVIDER HAS BEEN IDENTI-
5 FIED AS HAVING A PATTERN OF POOR PER-
6 FORMANCE.—

7 “(i) IN GENERAL.—In addition to the
8 report required under subparagraph (A),
9 the agency or entity with oversight author-
10 ity shall report to the Secretary the name
11 and address of any provider of services
12 with a pattern of poor performance.

13 “(ii) DETERMINATION OF PATTERN.—
14 The agency or entity with oversight au-
15 thority shall determine if a pattern of poor
16 performance exists with respect to a pro-
17 vider of services in accordance with the
18 definition of pattern of poor performance
19 developed by the Secretary under clause
20 (iii).

21 “(iii) DEVELOPMENT OF DEFINI-
22 TION.—The Secretary, in consultation with
23 national accrediting organizations and oth-
24 ers, shall develop a definition to identify a

1 provider of services with a pattern of poor
2 performance.

3 “(D) AUTHORITY TO WAIVE REPORTING
4 REQUIREMENT.—The Secretary may waive the
5 requirement to submit a report required under
6 this paragraph (but not a report regarding a
7 sentinel event that resulted in death required
8 under paragraph (3)) upon consideration of the
9 severity of the sentinel event.

10 “(3) ADDITIONAL REPORTING REQUIREMENTS
11 FOR SENTINEL EVENTS RESULTING IN DEATH.—In
12 addition to the report required under paragraph (1),
13 a provider of services shall report any sentinel event
14 resulting in death to—

15 “(A) the Secretary or the Secretary’s des-
16 ignee;

17 “(B) the State Attorney General or, upon
18 agreement with the State Attorney General, to
19 the appropriate law enforcement agency;

20 “(C) the State agency responsible for li-
21 censing the provider of services; and

22 “(D) the State protection and advocacy
23 system established pursuant to part C of title I
24 of the Developmental Disabilities Assistance

1 and Bill of Rights Act (42 U.S.C. 6041 et seq.)
2 for the State in which the event occurred.

3 “(4) RESPONSIBILITIES OF THE AGENCY OR
4 ENTITY WITH OVERSIGHT AUTHORITY.—Upon re-
5 ceipt of a report of a sentinel event that resulted in
6 death, the agency or entity with oversight authority
7 shall, in addition to the requirements of paragraph
8 (2)—

9 “(A) determine whether the death was re-
10 lated to the use of restraints or seclusion; and

11 “(B) notify the Secretary of the determina-
12 tion.

13 “(5) SANCTIONS FOR FAILURE TO REPORT.—

14 “(A) IN GENERAL.—The Secretary shall
15 establish sanctions, including intermediate sanc-
16 tions, as appropriate, for failure of a provider
17 of services or an agency or entity with oversight
18 authority to submit the reports and information
19 required under this subsection.

20 “(B) REMOVAL OF AGENCY OR ENTITY
21 WITH OVERSIGHT AUTHORITY.—The Secretary,
22 after notice to an agency or entity with over-
23 sight authority of a provider of services, as de-
24 termined in paragraph (1), and opportunity to
25 comply, may remove the agency or entity of

1 such authority if the agency or entity refuses
2 to submit the reports and information required
3 under this subsection.

4 “(6) LIABILITY FOR REPORTING.—An indi-
5 vidual, provider of services, agency, or entity shall be
6 liable with respect to any information contained in
7 a report required under this subsection if the indi-
8 vidual, provider of services, agency, or entity had
9 knowledge of the falsity of the information contained
10 in the report at the time the report was submitted
11 under this subsection. Nothing in the preceding sen-
12 tence shall be construed as limiting the liability of
13 an individual, provider of services, agency, or entity
14 for damages relating to the occurrence of a sentinel
15 event, including a sentinel event that results in
16 death.

17 “(7) NONDISCLOSURE OF ANALYSIS.—Notwith-
18 standing any other provision of law or regulation,
19 the root cause analysis developed under this sub-
20 section shall be kept confidential and shall not be
21 subject to disclosure or discovery in a civil action.

22 “(d) ESTABLISHMENT OR DESIGNATION OF SEN-
23 TINEL EVENTS DATABASE.—

24 “(1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this section, the Secretary

1 shall establish or designate a database of informa-
2 tion using the reports submitted under paragraphs
3 (2) and (3) of subsection (d) (in this subsection re-
4 ferred to as the ‘Sentinel Events Database’).

5 “(2) CONTENTS.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), the Sentinel Events Database shall
8 include the following:

9 “(i) The name and address of any
10 provider of services that is the subject of
11 a report submitted under subsection
12 (d)(3), if the agency or entity with over-
13 sight authority has determined that the
14 death was related to the use of restraints
15 or seclusion.

16 “(ii) The information reported by the
17 agency or entity under subparagraphs (B)
18 and (C) of subsection (d)(2).

19 “(B) CONFIDENTIALITY.—The Secretary
20 shall establish procedures to ensure that the
21 privacy of individuals whose treatment is the
22 subject of a report submitted under paragraph
23 (2) or (3) of subsection (d) is protected.

24 “(3) PROCEDURES FOR ENTRY OF INFORMA-
25 TION.—

1 “(A) IN GENERAL.—The Secretary shall—

2 “(i) prior to entry of information in
3 the Sentinel Events Database, disclose the
4 information to the provider of services that
5 is the subject of the information; and

6 “(ii) establish procedures to—

7 “(I) resolve disputes regarding
8 the accuracy of the information; and

9 “(II) ensure the accuracy of the
10 information.

11 “(B) NO DELAY OF SANCTIONS.—Any
12 sanction to be imposed by the Secretary against
13 a provider of services or an agency or entity
14 with oversight authority in relation to a sentinel
15 event shall not be delayed as a result of a dis-
16 pute regarding the accuracy of information to
17 be entered into the database.

18 “(4) ACCESS TO THE DATABASE.—

19 “(A) AVAILABILITY.—The Secretary shall
20 establish procedures for making the information
21 maintained in the Sentinel Events Database re-
22 lated to a sentinel event resulting in death, and
23 any reports of sentinel injuries arising from
24 those providers of services with a pattern of
25 poor performance identified in accordance with

1 subsection (d)(2)(C), available to Federal and
2 State agencies, national accrediting bodies,
3 health care researchers, and the public.

4 “(B) INTERNET ACCESS.—In addition to
5 any other procedures that the Secretary devel-
6 ops under subparagraph (A), the information in
7 the Sentinel Events Database shall be accessible
8 through the Internet.

9 “(C) FEES FOR DISCLOSURE.—

10 “(i) IN GENERAL.—Subject to clause
11 (ii), the Secretary may establish or approve
12 reasonable fees for disclosing information
13 maintained in the Sentinel Events Data-
14 base.

15 “(ii) NO FEE FOR FEDERAL AGEN-
16 CIES.—No fee shall be charged to a Fed-
17 eral agency for access to the Sentinel
18 Events Database.

19 “(iii) APPLICATION OF FEES.—Fees
20 collected under this clause shall be applied
21 by the Secretary toward the cost of main-
22 taining the Sentinel Events Database.”.

23 (2) EFFECTIVE DATE.—

24 (A) IN GENERAL.—Subject to subpara-
25 graph (B), the amendments made by this sub-

1 section take effect on the date of enactment of
2 this Act.

3 (B) REPORTING REQUIREMENTS.—The re-
4 porting requirements under section 1897(d) of
5 the Social Security Act, as added by paragraph
6 (1), shall apply to sentinel events occurring on
7 and after the date of enactment of this Act.

8 (b) INDIVIDUALS’ RIGHT TO FREEDOM FROM RE-
9 STRAINT AND REPORTING OF SENTINEL EVENTS UNDER
10 MEDICAID.—

11 (1) STATE PLANS FOR MEDICAL ASSISTANCE.—
12 Section 1902(a) of the Social Security Act (42
13 U.S.C. 1396a(a)) is amended—

14 (A) in paragraph (65), by striking the pe-
15 riod and inserting “; and”; and

16 (B) by adding at the end the following:

17 “(66) provide that the State will ensure that
18 any congregate care provider (as defined in section
19 1905(v)) that provides services to an individual for
20 which medical assistance is available shall—

21 “(A) protect and promote the right of each
22 individual to be free from physical or mental
23 abuse, corporal punishment, involuntary seclu-
24 sion, and any physical or chemical restraints

1 imposed for purposes of discipline or conven-
2 ience;

3 “(B) impose restraints only—

4 “(i) to ensure the physical safety of
5 the individual or other individuals; and

6 “(ii) upon the written order of a phy-
7 sician that specifies the duration and cir-
8 cumstances under which the restraints are
9 to be used (except in emergency cir-
10 cumstances specified by the Secretary until
11 such an order could reasonably be ob-
12 tained); and

13 “(C) submit the reports required under
14 subsection (d) of section 1897 (relating to sen-
15 tinel events) in the same manner as a provider
16 of services under that section is required to
17 submit such reports.”.

18 (2) DEFINITION OF CONGREGATE CARE PRO-
19 VIDER.—Section 1905 of the Social Security Act (42
20 U.S.C. 1396d) is amended by adding at the end the
21 following:

22 “(v) The term ‘congregate care provider’ means an
23 entity that provides hospital services, nursing facility serv-
24 ices, services of intermediate care facilities for the men-
25 tally retarded, hospice care, residential treatment centers

1 for children, services in an institution for mental diseases,
2 inpatient psychiatric hospital services for individuals
3 under age 21, or congregate care services under a waiver
4 authorized under section 1915(c).”.

5 (3) EFFECTIVE DATE.—

6 (A) IN GENERAL.—Subject to subpara-
7 graph (B), the amendments made by this sub-
8 section take effect on the date of enactment of
9 this Act.

10 (B) REPORTING REQUIREMENTS.—The re-
11 porting requirements under section
12 1902(a)(66)(C) of the Social Security Act (42
13 U.S.C. 1396a(a)(66)(C)), as added by para-
14 graph (1), shall apply to sentinel events occur-
15 ring on and after the date of enactment of this
16 Act.

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