

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.

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## 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

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## 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

(A), the agency or entity with oversight authority shall—

“(i) ensure that the provider—

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

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

“(III) establishes a time-limited plan or strategy, that allows the agency or entity with oversight authority to review and approve the analyses and any corrective actions proposed or made by the provider of services, to correct the problem or problems that resulted in the sentinel event, and to lead to risk reduction; and

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

“(2) REPORTS TO THE SECRETARY.—

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

“(B) INFORMATION TO BE REPORTED.—

“(i) IN GENERAL.—The report submitted under subparagraph (A) shall be submitted to the Secretary at regular intervals, but not less frequently than annually, and shall include—

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

“(II) a description of any corrective action taken by the providers of services with respect to the sentinel events or any other measures necessary to prevent similar sentinel events from occurring in the future;

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

“(IV) such additional information as the Secretary determines to be essential to ensure compliance with the requirements of this section.

“(ii) INFORMATION EXCLUDED.—The 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.

○