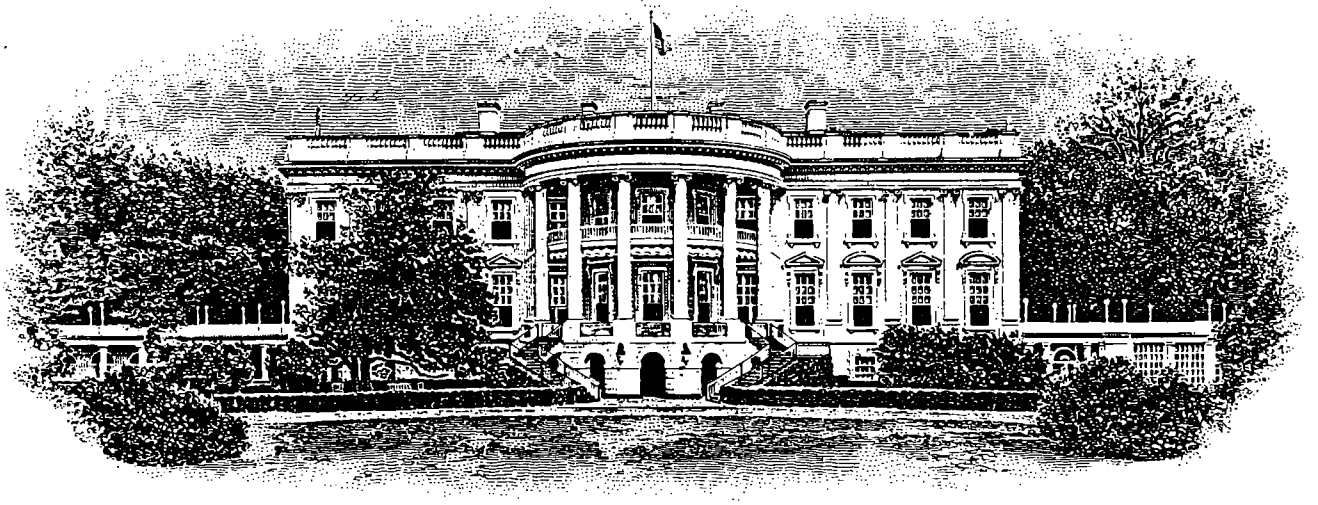
The White House



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Summary
HCFA letter

106TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. LIEBERMAN (for himself and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Freedom From Restraint Act of 1999".

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

"(1) protect and promote the right of each such individual to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience;

"(2) impose restraints—

"(A) only to ensure the physical safety of the individual or other individuals; and

"(B) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained); and

"(2) submit the reports required under subsection (c).

"(c) REPORTS.—

"(1) REPORTS TO AGENCIES OR ENTITIES WITH OVERSIGHT AUTHORITY.—

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

"(i) in the case of a provider of services participating in the program established under this title or the medicaid program under title XIX as a result of accreditation by a national accrediting body, the national accrediting body for that provider; and

"(ii) in the case of all other providers of services, the Secretary or, upon agreement between the Secretary and the relevant State, the State agency designated by the Secretary.

"(B) INVESTIGATION AND FURTHER REPORTING OF SENTINEL EVENTS.—Upon receipt 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) shall not identify any individual provider of services, practitioner, or individual.

"(C) ADDITIONAL REPORTING REQUIREMENTS WHEN A PROVIDER HAS BEEN IDENTIFIED AS HAVING A PATTERN OF POOR PERFORMANCE.—

"(i) IN GENERAL.—In addition to the report required under subparagraph (A), the agency or entity with oversight authority shall report to the Secretary the name

and address of any provider of services with a pattern of poor performance and any other information required by the Secretary.

"(ii) DETERMINATION OF PATTERN.—The agency or entity with oversight authority shall determine if a pattern of poor performance exists with respect to a provider of services in accordance with the definition of pattern of poor performance developed by the Secretary under clause (iii).

"(iii) DEVELOPMENT OF DEFINITION.—The Secretary, in consultation with national accrediting organizations and others, shall develop a definition to identify a provider of services with a pattern of poor performance.

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

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

"(A) the Secretary or the Secretary's designee;

"(B) the State Attorney General or, upon agreement with the State Attorney General, to the appropriate law enforcement agency;

"(C) the State agency responsible for licensing the provider of services; and

"(D) the State protection and advocacy system established pursuant to part C of title I of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.) for the State in which the event occurred.

"(4) RESPONSIBILITIES OF THE AGENCY OR ENTITY WITH OVERSIGHT AUTHORITY.—Upon receipt of a report of a sentinel event that resulted in death, the agency or entity with oversight authority shall, in addition to the requirements of paragraph (2)—

"(A) determine whether the death was related to the use of restraints or seclusion; and

"(B) notify the Secretary of the determination.

"(5) SANCTIONS FOR FAILURE TO REPORT.—The Secretary shall establish sanctions, including intermediate sanctions, as appropriate, for failure of a provider of services or an agency or entity with oversight authority to submit the reports and information required under this subsection.

"(6) LIABILITY FOR REPORTING.—An individual, provider of services, agency, or entity shall be liable with respect to any information contained in a report required under this subsection if the individual, provider of services, agency, or entity had knowledge of the falsity of the information contained in the report at the time the report was submitted under this subsection. Nothing in the preceding sentence shall be construed as limiting the liability of an individual, provider of services, agency, or entity for damages relating to the occurrence of a sentinel event, including a sentinel event that results in death.

"(7) NONDISCLOSURE OF ANALYSIS.—Notwithstanding any other provision of law or regulation, the root cause analysis developed under this sub-

section shall be kept confidential and shall not be subject to disclosure or discovery in a civil action.

"(d) ESTABLISHMENT OR DESIGNATION OF SENTINEL EVENTS RESTRAINTS DATABASE.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall establish or designate a database of information using the reports submitted under paragraphs (2) and (3) of subsection (c) (in this subsection referred to as the 'Sentinel Events Restraints Database').

"(2) CONTENTS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Sentinel Events Restraints Database shall include the following:

"(i) The name and address of any provider of services that is the subject of a report submitted under subsection (c)(3), if the agency or entity with oversight authority has determined that the death was related to the use of restraints or seclusion.

"(ii) The information reported by the agency or entity under subparagraphs (B) and (C) of subsection (c)(2).

"(B) CONFIDENTIALITY.—The Secretary shall establish procedures to ensure that the privacy of individuals whose treatment is the subject of a report submitted under paragraph (2) or (3) of subsection (c) is protected.

"(3) PROCEDURES FOR ENTRY OF INFORMATION.—

"(A) IN GENERAL.—The Secretary shall—

"(i) prior to entry of information in the Sentinel Events Restraints Database, disclose the information to the provider of services that is the subject of the information; and

"(ii) establish procedures to—

"(I) resolve disputes regarding the accuracy of the information; and

"(II) ensure the accuracy of the information.

"(B) NO DELAY OF SANCTIONS.—Any sanction to be imposed by the Secretary against a provider of services or an agency or entity with oversight authority in relation to a sentinel event shall not be delayed as a result of a dispute regarding the accuracy of information to be entered into the database.

"(4) ACCESS TO THE DATABASE.—

"(A) AVAILABILITY.—The Secretary shall establish procedures for making the information maintained in the Sentinel Events Restraints Database related to a sentinel event resulting in death, and any reports of sentinel injuries arising from those providers of services with a pattern of poor performance identified in accordance with subsection (c)(2)(C), available to Federal and State agencies, national accrediting bodies, health care researchers, and the public.

"(B) INTERNET ACCESS.—In addition to any other procedures that the Secretary develops under subparagraph (A), the information in the Sentinel Events Restraints Database shall be accessible through the Internet.

"(C) FEES FOR DISCLOSURE.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary may establish or approve reasonable fees for disclosing information maintained in the Sentinel Events Restraints Database.

"(ii) NO FEE FOR FEDERAL AGENCIES.—No fee shall be charged to a Fed-

cral agency for access to the Sentinel Events Restraints Database.

"(iii) APPLICATION OF FEES.—Fees collected under this clause shall be applied by the Secretary toward the cost of maintaining the Sentinel Events Restraints Database.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section take effect on the date of enactment of this Act.

(2) REPORTING REQUIREMENTS.—The reporting requirements under section 1897(c) of the Social Security Act, as added by subsection (a), shall apply to sentinel events occurring on and after the date of enactment of this Act.

SEC. 3. INDIVIDUALS' RIGHT TO FREEDOM FROM RESTRAINT AND REPORTING OF SENTINEL EVENTS UNDER MEDICAID.

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

(1) in paragraph (65), by striking the period and inserting "; and"; and

(2) by adding at the end the following:

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

"(A) protect and promote the right of each individual to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience;

"(B) impose restraints only—

"(i) to ensure the physical safety of the individual or other individuals; and

"(ii) upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained); and

"(C) submit the reports required under subsection (c) of section 1897 (relating to sentinel events) in the same manner as a provider of services under that section is required to submit such reports.".

(b) DEFINITION OF CONGREGATE CARE PROVIDER.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following:

"(v) The term 'congregate care provider' means an entity that provides hospital services, nursing facility services, services of intermediate care facilities for the mentally retarded, hospice care, residential treatment centers for children, services in an institution for mental diseases, or congregate care services under a waiver authorized under section 1915(c).".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section take effect on the date of enactment of this Act.

(2) REPORTING REQUIREMENTS.—The reporting requirements under section 1902(a)(66)(C) of the Social Security Act (42 U.S.C. 1396a(a)(66)(C)), as added by subsection (a), shall apply to sentinel events occurring on and after the date of enactment of this Act.

SEC. 2. INDIVIDUALS' RIGHT TO FREEDOM FROM RESTRAINT AND REPORTING OF SENTINEL EVENTS UNDER MEDICARE.

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

"INDIVIDUALS' FREEDOM FROM RESTRAINT AND REPORTING OF SENTINEL EVENTS

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

"(1) PROVIDER OF SERVICES.—The term 'provider of services' has the meaning given that term in section 1861(u), except that for purposes of this section the term includes a psychiatric hospital but does not include a home health agency.

"(2) SENTINEL EVENT.—The term 'sentinel event' means an unexpected occurrence involving an individual in the care of a provider of services for treatment for a psychiatric or psychological illness that results in death or serious physical or psychological injury that is unrelated to the natural course of the individual's illness or underlying condition.

"(b) PROTECTION OF RIGHT TO BE FREE FROM RESTRAINTS.—A provider of services eligible to be paid under this title for providing services to an individual entitled to benefits under part A or enrolled under part B (including an individual provided with a Medicare+Choice

Environment, we would group together those organizational activities the hospital must perform to support the delivery of patient care. We believe that this proposed format would embody the patient-centered focus of our proposed changes, emphasizing the continuous, integrated care processes that a patient experiences across all aspects of the hospital environment. Also, because functions and processes for delivering patient care often require interdisciplinary teamwork involving many hospital departments and services, the proposed regulations would incorporate a functional framework for the COPs rather than maintaining a stovepipe approach that gives the appearance that patient care activities can occur in isolation.

The complete proposed new organizational format for part 482 is as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart A—General Provisions

482.5 Basis and scope.
482.10 Condition of participation: Patient rights.

Subpart B—Patient Care Activities

482.15 Condition of participation: Patient admission, assessment, and plan of care.
482.20 Condition of participation: Patient care.
482.25 Condition of participation: Quality assessment and performance improvement.
482.30 Condition of participation: Diagnostic and therapeutic services or rehabilitative services.
482.35 Condition of participation: Pharmaceutical services.
482.40 Condition of participation: Nutritional services.
482.45 Condition of participation: Surgical and anesthesia services.
482.50 Condition of participation: Emergency services.
482.55 Condition of participation: Discharge planning.

Subpart C—Organizational Environment

482.110 Condition of participation: Administration of organizational environment.
482.115 Condition of participation: Infection control.
482.120 Condition of participation: Information management.
482.125 Condition of participation: Human resources.
482.130 Condition of participation: Physical environment.
482.135 Condition of participation: Life safety from fire.
482.140 Condition of participation: Blood and blood product transfusions.
482.145 Condition of participation: Potentially infectious blood and blood products.
482.150 Condition of participation: Utilization review.

Subpart D—Requirements for Specialty Hospitals

482.155 Special provisions applying to psychiatric hospitals.
482.160 Condition of participation: Special medical record requirement for psychiatric hospitals.
482.165 Condition of participation: Special staff requirements for psychiatric hospitals.
482.170 Special requirements for hospital providers of long-term care services ("swing-beds").

We note that although we are proposing no changes to the requirements for specialty hospitals, the existing requirements would be redesignated numerically to accommodate the proposed changes to the preceding COPs.

B. Discussion of Proposed Conditions

1. Basis and Scope (§ 482.1)

We are proposing to add a new paragraph (a)(6) to the statutory basis section for part 482 that sets forth, under section 1138 of the Act, requirements for hospital protocols for organ procurement and standards for organ procurement agencies' agreements with hospitals for organ procurements. This provision will further the authority governing organ procurements.

2. Patient Rights (§ 482.10)

Under section 1861(e)(9) of the Act, an institution may be recognized by Medicare as a hospital only if, in addition to meeting the specific requirements in the preceding sections of that provision, it meets such other requirements as the Secretary finds necessary in the interest of patient health and safety. In our view, patient health and safety cannot be protected simply by avoiding obvious risk factors such as poor infection control practices or inadequate nurse staffing (as documented in recent literature on the effects of Nursing on patient outcomes such as morbidity, mortality, length of stay, and cost—see Keeler, E., *et al.*, "Hospital Characteristics and Quality of Care," *JAMA* 268 (1992): 1709–1714.; and Krakauer, H., *et al.*, "Evaluation of the HCFA for the Analysis of Mortality Following Hospitalization," Health Services Research 27 (1992): 317–335). Patient rights dealing with freedom from physical or verbal abuse, harassment, or inappropriate restraints are examples of direct protections of patients' physical and emotional health and safety. In addition, patients' successful recoveries from illness or injury depend on many factors related to their psychological and emotional health, including their general feeling of well-being. Because of the importance of these psychological and emotional factors, we believe patient health and safety can be protected adequately only if patient care is delivered in an atmosphere of respect for the individual patient's comfort, dignity, and privacy.

This view is shared by other parties involved in the development of these conditions of participation, many of whom expressed strong support for the inclusion of specific provisions addressing patient rights. Therefore, we propose to set forth a new condition of participation that would recognize explicitly that a hospital must protect and promote certain patient rights.

The proposed condition is composed of five standards. The first proposed standard would require that a hospital inform each patient of his or her rights in advance of furnishing care. It also would require that a hospital have a grievance process and must indicate who a patient should contact if he or she desires to express a grievance. We are not proposing a specific method as to how a hospital should notify each patient of his or her rights, or establishing structural or procedural expectations about how a hospital's patient grievance process should be set up. Instead, we believe each hospital should implement a patient rights policy that reflects its specific manner of operations and minimizes administrative burden, as long as the hospital meets the underlying expectation that it informs patients about their rights and about whom to contact when patients believe these rights have been violated.

The remaining four proposed standards under the patient rights condition would establish a minimum set of required patient rights. In developing these provisions, we closely examined the regulations concerning patient rights for other provider types, such as nursing homes and HHAs. Because the nature of patient care varies among provider types, we are proposing only those patient rights that we believe are appropriate and necessary in the hospital setting. Based on the strong support from all parties involved in the development of these proposed hospital conditions, we are proposing that a patient should have the following rights:

- The right to be informed of his or her rights, to participate in the development and implementation of the individual's plan of care, and to make decisions regarding that care.

• The right to formulate advance directives and to have those directives followed.

• The right to privacy and to receive care in a safe setting.

• The right to be free from verbal or physical abuse or harassment.

• The right to confidentiality of his or her clinical records.

• The right to access information contained in his or her clinical records within a reasonable time.

• The right to be free from the use of seclusion and restraints as a means of coercion, convenience, or retaliation by staff. If seclusion or restraints are used (including psychopharmacological drugs used as restraints) they must be used in accordance with a patient's plan of care and may be used only as a last resort and in the least restrictive manner possible, to protect the patient or others from harm. Restraints must be removed or seclusion ended at the earliest possible time.

We believe these proposed patient rights are clearly necessary in the interest of patient health and safety and are for the most part self-explanatory. We note that the rights concerning advance directives are tied directly to the statute (section 1866(f) of the Act), and the hospital's responsibilities in these areas are more fully described in other sections of the regulations (see existing § 489.102). However, we believe it is appropriate to reference advance directives in the proposed patient rights section, consistent with the reference to advance directives in the patient rights sections of the existing regulations for both nursing homes and HHAs.

We considered proposing a specific time period within which a hospital would be required to provide access to requested medical records under proposed § 482.10(d)(2), but concluded that the proposed requirement that a hospital provide access to such information within a "reasonable" time is more feasible. If a former patient requests access to 3-year-old closed medical records, which could be in storage, a "reasonable" time to retrieve them likely would be longer than if the spouse (with appropriate power of attorney) of an inpatient requests to see the medical records of her or his spouse who is still in the hospital. In the former case, a "reasonable" time might be measured in days, whereas it could be hours in the latter example. Thus, we believe that "reasonable" must be defined in terms of the individual circumstances. Most important, we believe that "reasonable" means that the hospital will not frustrate the legitimate efforts of individuals to gain access to their own medical records and will actively seek to meet those requests as quickly as its recordkeeping system permits. If a hospital receives complaints from patients or their legal representatives about delays in gaining access to properly requested records, we would expect that the hospital would both respond quickly to resolve the complaints and consider the complaints as an opportunity for improvement as part of its quality assessment and performance improvement program. In summary, we believe that the use of the word "reasonable" sets the proper performance standard for the hospital without imposing an arbitrary burden, while at the same time enabling surveyors to take action if a hospital is systematically frustrating legitimate efforts to gain access to medical records. We welcome comments on the appropriateness of our decision not to propose any specific timeframe for providing access to a patient's records.

We also strongly considered expanding the proposed patient rights provisions (or establishing separate requirements) to provide further detail related to a patient's right to be free from seclusion or restraints. We recognize that the use of restraints or seclusion has the potential to produce serious consequences for a patient's health and safety, such as physical and psychological harm, loss of dignity, violation of civil rights, and even death. Thus, our expectation is that a hospital would impose restraints or seclusion only when absolutely necessary to prevent immediate injury to the patient or others and when no alternative means are sufficient to accomplish this purpose. We also expect that when restraints or seclusion are used, the plan of care should address how and when such practices are to be employed, and patients placed under restraints or in seclusion would be released as soon as they no longer pose an immediate threat of injury to themselves or others. Although we have built these expectations into the proposed patient rights provisions, the question remains whether it would be advisable to add further, more prescriptive requirements concerning the use of seclusion or restraints. One possibility would be to incorporate into the regulations a series of specific requirements governing the use of restraints and seclusion, as detailed below:

• Seclusion or restraints may only be used to the extent authorized by the signed order of a physician. Written authorization must include the date and time of the order, and the reason for seclusion or restraint. For restraint, the order must include the type of restraint(s) and the number of restraint points.

• Each order for seclusion or restraints must be in writing, must be time-limited and specify start and end times. Implementing a time-limited order does not require applying the intervention for the entire period if the patient demonstrates a reduction or change in the behavior that led to being placed in restraint or seclusion.

• A renewal order may be issued if the physician clinically assesses the patient face to face and determines that seclusion or restraint continues to be necessary to prevent injury to self or others, and there is no less restrictive method of preventing the injurious behavior.

• Orders for seclusion or restraint must never be written on a standing or as needed basis.

• Written orders for restraint and seclusion for adults must be valid for no more than 6 hours; written orders for restraint and seclusion for children and adolescents must be valid for no more than 2 hours.

• A patient in seclusion or restraint must be checked by a person trained in the use of restraints and seclusion at least every 15 minutes for comfort, body alignment, circulation, hydration, feeding, and toilet needs. A patient in seclusion or restraint must have vital signs checked a minimum of every 2 hours. Written documentation of checks must include, at a minimum, the name of the person doing the check, the date and time of the check, and the patient's condition.

For purposes of this proposed rule, we have opted not to set forth these kinds of detailed requirements in the regulations but instead to require that a hospital achieve the intended outcome that restraints or seclusion are never imposed inappropriately, without limiting a hospital's flexibility in how it meets this requirement. However, we welcome comments on the prevalence of the use of restraints and seclusion in the hospital setting and whether the above standards, or alternative requirements, are needed to ensure patient health and safety.

Subpart B—Patient Care Activities

3. Patient Admission, Assessment, and Plan of Care (§ 482.15)

The first proposed condition under proposed Subpart B, Patient Care Activities, would combine the requirements for patient admission, assessment, and care plan development in a single condition, which would be followed by a separate condition on patient care. We believe this

THE FREEDOM FROM RESTRAINT ACT OF 1999

SUMMARY OF THE NEW LEGISLATION

This legislation would essentially expand the requirements governing the use of restraints and seclusion in nursing homes to include hospitals participating in the Medicare and Medicaid program and intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children and institutions of mental disease participating in the Medicaid program. This new legislation would allow these facilities to impose physical restraints only upon the written order of a physician and only when necessary to ensure the physical safety of the patient or of other patients. Providers would be required to report all instances of serious patient injury or death related to the use of restraints to a central database to be established by the Secretary. HHS would be required to ensure that the provider investigated the cause of the patient injury and death and established a strategy to prevent similar injuries.

SUMMARY OF THE HARTFORD CASES

The Freedom From Restraint Act of 1999 was inspired by a series of cases in Connecticut during October of 1998 in which several mentally ill children residing in psychiatric institutions died after being restrained by facility staff. The Harvard Center for Risk Analysis estimates that between 50 and 150 such deaths occur annually across the country. Reports indicated that many of the restraints being used routinely in the Connecticut facilities are not supposed to be used as part of patient care. A number of the patients died in the same type of a restraint hold, in which a patient is restrained face down on the floor, with their arms crossed beneath them and a staff member exerting pressure on their backs. In addition, there were indications that the restraining holds were not used as a last resort, but rather as a routine method of discipline. For instance, one of the children who died was restrained because he became upset after he was unable to find his favorite teddy bear.

HCFA PROPOSAL

HCFA has been aware of patient advocate concerns about the inappropriate use of restraints for over a year. In response, HHS published an NPRM in December of 1997 that proposed to modify the Medicare Conditions of Participation for hospitals to prohibit the use of seclusion or restraints except when in accordance with a patient's plan of care and should be used only as a last resort. Providers would be required to use restraints in the least restrictive manner possible and must be removed at the earliest possible time.

At this point, despite the fact that comments were submitted to the agency in April of 1998, HCFA has not taken steps to codify these conditions of participation into a final rule. However, because of the importance of this issue to the health and safety of patients, HCFA will carve out the Patients Rights section of the new Conditions of Participation. This section, which addresses the use of restraints, will be published in final form by late summer.

On a staff level, HCFA has objected to Senator Lieberman's proposal to create a centralized database to track patient deaths and injuries caused by the inappropriate use of restraints because of privacy concerns.

THE NEW LEGISLATION BUILDS ON HCFA'S CURRENT AUTHORITY

Currently, HCFA only has authority to require Medicare and Medicaid hospitals to comply with the standards for the use of restraints proposed in the NPRM. Senator Lieberman's proposed legislation would provide HCFA with the authority to require intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children, and institutions of mental disease that are participating in the Medicaid program to comply with stricter standards around the use of patient restraints.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Identical letter sent to Lieberman

The Administrator
Washington, D.C. 20201

MAR 2 4 1999

The Honorable Christopher J. Dodd
United States Senate
Washington, D.C. 20510

Dear Senator Dodd:

I am writing in strong support of your efforts to provide additional Federal oversight to prevent inappropriate seclusion and restraint practices in mental health settings. The President, Secretary Shalala, and I share your concern over the recent reports of children who died after being inappropriately restrained, and we applaud your efforts to protect all hospital patients from harm associated with the use of seclusion and restraints. We look forward to working with you on the specifics of the legislation as it moves forward.

I would also like to take this opportunity to update you on the Administration's recent efforts to protect children and other hospital patients from harm associated with the inappropriate use of restraints. As you may know, in the Notice of Proposed Rulemaking (NPRM) for the new Medicare hospital Conditions of Participation (CoP), HCFA proposed a CoP to address patients' rights. Within this CoP, HCFA proposed standards restricting for the first time, the use of restraints in hospital settings. The Medicare hospital CoPs apply to all patients in hospitals who participate in the Medicare program, therefore, these rights extend beyond the Medicare population in these facilities. In addition, the hospital CoPs apply to Medicaid hospitals as well.

Because of the importance of this issue to the health and safety of patients, we plan to carve out the "Patients Rights" section (which addresses the seclusion/restraint issue) of the CoP from the larger hospital conditions of participation regulation so that we can publish the standard in final by late summer. By carving out this section, HCFA will be able to move more quickly to hold all hospitals that participate in Medicare and Medicaid accountable for the inappropriate use of seclusion and restraints. The proposed Patient Rights CoP will apply to all participating hospitals, including acute, psychiatric, rehabilitation, long-term, children's, and alcohol-drug hospitals.

In addition to our efforts with hospitals, HCFA already has regulations restricting the use of restraints in settings including intermediate care facilities for the mentally retarded (ICFs-MR) and nursing facilities. In addition, the Clinton Administration has made improving the quality of nursing home care and oversight a top priority. Last July, the President announced a broad initiative to strengthen the enforcement of our nursing home regulations, which we published in 1995.

The Honorable Christopher J. Dodd

In addition to HCFA's efforts, a number of other federal agencies are increasing attention to inappropriate seclusion and restraint practices. Most notably, the Center for Mental Health Services (CMHS) of the Substance Abuse and Mental Health Services (SAMHSA) Administration within the U.S. Department of Health and Human Services provides funds to state protection and advocacy systems. These systems, present in each state, have a strong record of addressing and resolving consumer complaints related to the misuse of seclusion and restraint. Moreover, HCFA staff are actively participating with CMHS in the development and implementation of an action plan that will continue to address problems with the misuse of seclusion and restraints in our nation's health care facilities.

Your legislation will add to these efforts by expanding the scope of this policy to patients in settings that HCFA does not have the authority to regulate such as residential treatment centers for children and congregate care services under a waiver authorized under section 1915(c). Your bill also emphasizes the need for more accurate and timely reporting through the establishment or designation of sentinel events restraint database. We look forward to working with you and with your staff on this approach.

The President, Secretary Shalala, and I strongly support your interest and efforts and those of your colleagues to prevent the inappropriate and dangerous use of restraints in mental health settings, and I am confident that we can work together to protect the children and other vulnerable patients who are currently at risk.

Sincerely,

Nancy-Ann DeParle

Nancy-Ann Min DeParle
Administrator

THE FREEDOM FROM RESTRAINT ACT OF 1999

SUMMARY OF THE NEW LEGISLATION

This legislation would essentially expand the requirements governing the use of restraints and seclusion in nursing homes to include hospitals participating in the Medicare and Medicaid program and intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children and institutions of mental disease participating in the Medicaid program. This new legislation would allow these facilities to impose physical restraints only upon the written order of a physician and only when necessary to ensure the physical safety of the patient or of other patients. Providers would be required to report all instances of serious patient injury or death related to the use of restraints to a central database to be established by the Secretary. HHS would be required to ensure that the provider investigated the cause of the patient injury and death and established a strategy to prevent similar injuries.

SUMMARY OF THE HARTFORD CASES

The Freedom From Restraint Act of 1999 was inspired by a series of cases in Connecticut during October of 1998 in which several mentally ill children residing in psychiatric institutions died after being restrained by facility staff. The Harvard Center for Risk Analysis estimates that between 50 and 150 such deaths occur annually across the country. Reports indicated that many of the restraints being used routinely in the Connecticut facilities are not supposed to be used as part of patient care. A number of the patients died in the same type of a restraint hold, in which a patient is restrained face down on the floor, with their arms crossed beneath them and a staff member exerting pressure on their backs. In addition, there were indications that the restraining holds were not used as a last resort, but rather as a routine method of discipline. For instance, one of the children who died was restrained because he became upset after he was unable to find his favorite teddy bear.

HCFA PROPOSAL

HCFA has been aware of patient advocate concerns about the inappropriate use of restraints for over a year. In response, HHS published an NPRM in December of 1997 that proposed to modify the Medicare Conditions of Participation for hospitals to prohibit the use of seclusion or restraints except when in accordance with a patient's plan of care and should be used only as a last resort. Providers would be required to use restraints in the least restrictive manner possible and must be removed at the earliest possible time.

At this point, despite the fact that comments were submitted to the agency in April of 1998, HCFA has not taken steps to codify these conditions of participation into a final rule. However, because of the importance of this issue to the health and safety of patients, HCFA will carve out the Patients Rights section of the new Conditions of Participation. This section, which addresses the use of restraints, will be published in final form by late summer.

On a staff level, HCFA has objected to Senator Lieberman's proposal to create a centralized database to track patient deaths and injuries caused by the inappropriate use of restraints because of privacy concerns.

THE NEW LEGISLATION BUILDS ON HCFA'S CURRENT AUTHORITY

Currently, HCFA only has authority to require Medicare and Medicaid hospitals to comply with the standards for the use of restraints proposed in the NPRM. Senator Lieberman's proposed legislation would provide HCFA with the authority to require intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children, and institutions of mental disease that are participating in the Medicaid program to comply with stricter standards around the use of patient restraints.