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MENTAL HEALTH

Improper Restraint or Seclusion Use Places People at Risk



**Health, Education, and
Human Services Division**

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The Honorable Joseph I. Lieberman
The Honorable Christopher J. Dodd
The Honorable Daniel Patrick Moynihan
The Honorable Pete V. Domenici
United States Senate

The Honorable Nancy L. Johnson
The Honorable Christopher Shays
The Honorable James H. Maloney
The Honorable Sam Gejdenson
The Honorable Rosa L. DeLauro
The Honorable Pete Stark
House of Representatives

People with serious mental illness or mental retardation are among the country's most vulnerable citizens. About 5.5 million adults experience severe mental illness each year—with about 240,000 requiring either inpatient treatment in mental hospitals or residential treatment in centers or group homes. An estimated 120,000 individuals with mental retardation lived in intermediate care facilities, while about 240,000 others lived in smaller residential settings in 1998. While states, insurance companies, and patients and their families pay for some of this treatment, Medicare, the federal health insurance program for the elderly and disabled, and Medicaid, the federal and state health insurance program for the poor, also pay for treatment of eligible individuals.

Patient advocates and recent press coverage report that some of these individuals are at risk of injury or death in inpatient or residential treatment facilities as a result of improper restraint or seclusion practices. The Hartford Courant reported that patient deaths were related to the use of restraint or seclusion¹ in 142 cases over the past 10 years in several types of residential treatment settings across the country.²

Concern over these reports has led to the introduction of proposed legislation and your request that we conduct a study to assist you in your legislative deliberations. Specifically, you asked us to

¹Restraint is the partial or total immobilization of a person through the use of drugs, mechanical devices such as leather cuffs, or physical holding by another person. Seclusion is involuntary confinement in a room that the person is physically prevented from leaving.

²The Hartford Courant (Oct. 11-15, 1998).

- determine the dangers of restraint and seclusion, the extent to which restraint and seclusion are used in inpatient and residential treatment facilities for individuals with mental illness or mental retardation, and the number of related injuries and deaths;
- identify the federal and state policies that govern the use of restraint and seclusion in inpatient or residential treatment facilities for individuals with mental illness or mental retardation; and
- describe the experiences of states that have instituted regulations and reporting requirements to address the use of restraint and seclusion.

To do this study, we reviewed federal regulations for Medicaid and Medicare and regulations from selected states that affect individuals with mental illness or mental retardation in inpatient or residential treatment facilities. Following meetings with experts, provider representatives, patient advocates, and government officials, we identified and reviewed relevant data sources. To gain at least a partial indication of the scope of the problem, we obtained data on the number of deaths related to restraint or seclusion investigated by the Protection and Advocacy agencies (P&A)³ in all 50 states and the District of Columbia in fiscal year 1998. To obtain insights into the effects of different reporting requirements and other policies regarding restraint and seclusion use, we conducted field work in Delaware, Massachusetts, New York, and Pennsylvania—states that either have reduced restraint use in their public mental health facilities or have imposed more comprehensive reporting requirements. We also met with officials from the Health Care Financing Administration (HCFA), the federal agency that administers Medicare and Medicaid, and the Substance Abuse and Mental Health Services Administration (SAMHSA).

As agreed, we focused our inquiry on the population receiving services for mental illness or mental retardation in residential facilities that receive public funding, primarily from Medicare and Medicaid. We did not specifically address outpatient treatment programs, sheltered workshops, schools, drug and alcohol rehabilitation programs, or correctional facilities. We excluded from our review restraints used to facilitate medical procedures, prevent interference with medical equipment such as feeding tubes, or provide postural support. We did not independently audit the rates of restraint use provided to us by states cited in this report. We conducted our work between March and July 1999 in accordance with generally accepted government auditing standards.

³P&As for individuals with mental illness were established or designated by states pursuant to the Protection and Advocacy for Individuals With Mental Illness Act of 1986, as amended, 42 U.S.C. 10801 et seq.

Results in Brief

Improper restraint and seclusion can be dangerous to both people receiving treatment and staff, but the full extent of related injuries and deaths is unknown. There is no comprehensive reporting system to track such injuries and deaths or the rates of restraint and seclusion use by facility. Our telephone survey of 51 state P&As found that only 15 states have any systematic reporting to alert these agencies to any deaths that occur among individuals in residential treatment settings. Even these reporting systems are not comprehensive, because most agencies that receive reports get them only from state facilities. Additionally, P&As sometimes have difficulty getting access to medical records, which prevents them from thoroughly investigating such incidents. On the basis of the partial information available from these 51 agencies, we identified 24 deaths associated with restraint or seclusion during fiscal year 1998. Because reporting is so fragmentary, we believe many more deaths related to restraint or seclusion may occur. Data on use of restraint and seclusion are also fragmentary because most facilities are not required to report these data to oversight agencies.

Federal and state regulations governing restraint and seclusion for individuals with mental illness and mental retardation are inconsistent across types of facilities. The federal government regulates the use of restraint and seclusion in nursing homes and Intermediate Care Facilities for the Mentally Retarded, but until recently, no federal regulations governed their use in other facilities, such as psychiatric hospitals, residential treatment centers for children, or community group homes. In July 1999, HCFA issued an interim final rule with revised Medicare conditions of participation for hospitals that address restraint and seclusion use. Although this is a positive step, people in residential treatment centers and group homes participating in the Medicaid Home and Community-Based Waiver program have limited federal protection. While some states have regulations in place governing the use of restraint and seclusion, often these regulations do not apply to privately operated facilities.

On the basis of the experience of several states, having regulatory protections and reporting requirements can reduce the use of restraint and seclusion and improve safety for patients and staff. For example, Pennsylvania reduced the use of restraint and seclusion by over 90 percent between 1993 and 1999 in state mental health facilities. And Delaware's state Intermediate Care Facility for the Mentally Retarded introduced an initiative under Medicaid that reduced the state's restraint use by 81 percent between 1994 and 1997. Typically, successful strategies to

reduce the use of restraint and seclusion have similar components: defined principles and policies that clearly outline when and how restraint or seclusion may be used; strong management commitment and leadership; a requirement to report the use of restraint or seclusion; staff training in safe use of, and alternatives to, restraint and seclusion; and oversight and monitoring. To improve patient safety, we believe HCFA should, at a minimum, consider extending the same policies—tailored to the needs of individuals—on the use of restraint and seclusion that now protect individuals in long-term care and hospitals to people in any treatment setting funded by Medicare and Medicaid. We also recommend that HCFA improve reporting of restraint and seclusion use and any related deaths or injuries and require staff training in safely applying restraint or seclusion as well as alternative methods for dealing with potentially violent situations.

Background

Clinicians, providers, and patient advocates generally agree that when patients lose control to the extent that they or others are at imminent risk of physical harm, staff may legitimately restrain or seclude them on an emergency basis. Far less agreement exists about the use of restraint and seclusion in any other situation. For people with psychiatric problems, some clinicians consider seclusion to be an appropriate early intervention strategy to reduce overstimulation, teach self-control, and protect the treatment setting. For people with mental retardation, seclusion is generally not considered appropriate, but some clinicians consider restraint to be a legitimate part of a behavioral treatment plan, for example, as a way to reduce self-injuring behavior. However, many patient advocates, state mental health program officials, and representatives of the psychiatric nursing profession disagree. While they accept that restraint may be needed in some cases, they consider it an emergency response to a treatment failure to be used only as a last resort.

People with mental illness or mental retardation may receive residential treatment, and may be subject to restraint and seclusion, in a variety of settings. People with psychiatric conditions may receive inpatient treatment in traditional state hospitals, private psychiatric hospitals, or community hospitals with psychiatric units. Many of the advocates and clinicians we met with indicated that deinstitutionalization of individuals with less serious mental illness has resulted in an inpatient population with more severe mental illness.

Federal funding, primarily federal Medicare and federal/state Medicaid programs, accounts for about 40 percent of the revenue for mental health treatment facilities. Medicare provides limited mental health coverage for individuals over age 65 and those under 65 who are disabled. In 1994, Medicare spent about \$4.5 billion for mental health services in either private psychiatric hospitals or general hospitals.

The Medicaid program covers children with mental illness under the age of 21 and, at state option, adults aged 65 and older with mental illness and adults and children with mental retardation. Medicaid provides inpatient mental health services for children under 21 years old in general hospitals, psychiatric hospitals, and nonhospital settings. Individuals aged 65 and older may receive inpatient mental health services in a hospital or nursing home. Medicaid spending for inpatient psychiatric treatment totaled over \$2 billion in fiscal year 1996. In fiscal year 1996, Medicaid spent about \$9.6 billion for Intermediate Care Facilities for the Mentally Retarded (ICF/MR), which provide long-term residential care and treatment for people with mental retardation. In addition, Medicaid covers care for children with mental illness and adults and children with mental retardation in less restrictive settings via the home and community-based waiver program. These waivers allow states the flexibility to cover a broader range of services in less restrictive settings such as group homes. State Medicaid programs spent \$5.6 billion in federal and state funding on home and community-based waiver services in fiscal year 1996, some of which was used to provide residential treatment for this population.

HCFA defines federal requirements for facilities to participate in the Medicare and Medicaid programs. For long-term care and ICF/MR facilities, HCFA contracts with states to survey facilities and certify that they meet federal requirements. Most general and psychiatric hospitals are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or other accrediting bodies, and HCFA accepts this as proof of meeting federal requirements for these facilities. For two additional conditions of participation for psychiatric hospitals, a separate state survey is periodically performed.

Following discovery of severe patient neglect and abuse at a state-run facility for individuals with mental retardation in New York, the Congress in 1975 enacted what has become known as the Developmental Disabilities Assistance and Bill of Rights Act. This act requires states, as a condition for receiving federal assistance, to have in effect a protection and advocacy system for people with developmental disabilities. In 1985,

congressional hearings detailed reports of appalling conditions in psychiatric hospitals, and the following year the Congress enacted what is known today as the Protection and Advocacy for Individuals With Mental Illness Act. This law requires states to establish or designate P&As for people with mental illness. Most P&As are independent of state government, though a few are state agencies. In most states, the same P&A serves both individuals with mental illness and those with mental retardation. The P&As are charged with investigating reports of abuse or neglect of individuals with developmental disabilities or mental illness in institutional care and are empowered to pursue legal and administrative remedies.

Incomplete Reporting Leaves Full Extent of Patient Risk Unknown

While restraint and seclusion use can injure patients and staff, the full extent of that risk is not known because reporting is so fragmentary. Our survey of state P&As identified 24 deaths during fiscal year 1998 related to restraint or seclusion. However, this is likely to understate the problem, because the lack of comprehensive reporting makes it impossible to determine all deaths in which restraint or seclusion was a factor. Of 51 P&As, only 15 receive reports of deaths in residential treatment settings on a systematic basis, and many P&As reported having difficulty obtaining the documents needed to pursue their investigations. HCFA requires reporting of deaths and the use of restraint and seclusion in some, but not all, types of Medicaid or Medicare residential facilities that serve adults and children with mental illness and mental retardation. State reporting requirements vary, and not all states require facilities to report restraint-related deaths to the state licensing authority. JCAHO—the principal accrediting body for Medicare-certified hospitals—encourages voluntary reporting of sentinel events such as deaths and injuries related to restraint or seclusion and collects information on the sentinel events reported. It does not compile data on the use of restraint and seclusion in its accredited facilities.

Restraint and Seclusion Use Can Injure Patients and Staff

Restraint and seclusion can be dangerous to individuals in treatment settings because restraining them can involve physical struggling, pressure on the chest, or other interruptions in breathing. JCAHO reviewed 20 restraint-related deaths and found that in 40 percent the cause of death was asphyxiation, while strangulation, cardiac arrest, or fire caused the remainder. Among the deaths reported by the Hartford Courant as cases in which restraint or seclusion was a factor, the causes of death included asphyxia, cardiac complications, drug overdoses or interactions, blunt

trauma, strangulation or choking, fire/smoke inhalation, and aspiration (breathing vomit into the lungs).

Recent incidents reported by the National Alliance for the Mentally Ill and P&As included the following:

- A 36-year-old man died in November 1998 from cardio-respiratory failure caused by extreme agitation after being restrained by eight staff members and bound in leather restraints.
- In May 1997, a 35-year-old man who was doing yard work with a staff member at a group home became agitated, pushed the staff member, and walked away. The staff member pursued the man and placed him in a basket hold. (A basket hold consists of crisscrossing a person's arms over his or her chest and holding them from behind. This hold compresses the chest and also prevents the staff member from observing the person's face and breathing). The staff member wrapped his arms around the man's chest and took this man down to his knees, then face down on the ground. This action compressed the man's chest and killed him.

Children are subjected to restraint and seclusion at higher rates than adults and also are at greater risk of injury. Several of the states that took part in a study sponsored by the Center for Mental Health Services indicated they had higher restraint rates for children, including one state in which children in state-run inpatient facilities were restrained four times more frequently than adults. Children are smaller and weaker than adults, so staff who are used to overpowering adults may apply too much pressure or force when restraining children. The following cases reported by the National Alliance for the Mentally Ill illustrate the dangers of restraint to children:

- In February 1999, a 16-year-old girl died of respiratory arrest in California while being restrained by four staff members with her face on the floor.
- The use of basket holds was involved in the deaths of a 17-year-old girl in a Florida residential treatment center in November 1998 and a 9-year-old boy, who died in March 1999 in North Carolina after being restrained in a basket hold following a period of seclusion.

People are at particular risk if they have a combination of conditions, such as both mental retardation and mental illness, or mental illness and substance abuse. People with both mental illness and mental retardation often are not in specialized programs to address their unique needs and instead may be placed in either psychiatric hospitals or facilities for

people with mental retardation only. In one state hospital system, treatment plans for these patients included extensive use of restraint and seclusion, including several patients who were kept in either restraint or seclusion 24 hours a day. These and other practices were the subject of a class action suit, which resulted in implementation of a monitoring procedure.

Many advocates we spoke with indicated that restraining individuals who are on certain medications can be risky. For example, a commonly prescribed antidepressant may result in metabolic problems when a patient's movement is restricted, which may lead to life-threatening hyperthermia. Clinicians have postulated that potentially fatal cardiac arrhythmia can result from the combination of certain drugs and the adrenaline produced by an individual's agitation and physical struggle while being restrained. For example, a 48-year-old man in Texas was placed in a straitjacket and tied to a chair. Although 15-minute checks were required, they were not performed, and he was found dead the next day. The cause of death was listed as an overdose of imipramine, an antidepressant. The medical examiner stated that the restraints contributed to his death by affecting his ability to metabolize the medicine.

The use of restraint or seclusion also can result in serious injury or abuse. During fiscal year 1998, P&As received about 1,000 complaints regarding restraint and seclusion and documented numerous instances of bruising and broken bones. In one instance, a 24-year-old man suffered a severe fracture in the right arm while being put into restraints by staff. He was subsequently left in four-point restraints⁴ for 12 hours, despite his requests for medical attention. Other examples of excessive or abusive restraint use reported by the National Alliance for the Mentally Ill and the P&As included the following:

- An 18-year-old man in a New York psychiatric hospital was tackled to the floor by five staff members, hit in the face, and then placed in restraints in February 1998.
- A woman was kept in seclusion for over 30 hours in an Oregon hospital in December 1998 without being allowed to use the bathroom or contact a relative. She eventually began screaming, and staff held her down by placing a knee to her neck and injected her with medicine.
- In February 1999, a man in a Missouri state psychiatric hospital was restrained for 21 days and secluded for 30 days. As a result of the long periods of restraint, he developed kidney problems and lost muscle tone.

⁴Four-point restraints immobilize a person on a bed with a cuff around each wrist and ankle.

Even if no physical injury is sustained, people in treatment settings can be severely traumatized during restraint, especially those who had been sexually abused in the past. A Massachusetts task force investigating this issue reported that research indicates at least half of all women treated in psychiatric settings have a history of physical or sexual abuse. The task force found that the use of restraints on people who have been abused often results in those people reexperiencing the trauma and causes setbacks in treatment. The task force's report recommended that staff should identify patients who have been abused and use only certain forms of restraint and seclusion on these patients when necessary, avoiding forms such as mechanical restraints that place a person in a spread-eagle position.⁵

While the people in treatment are at risk during episodes of restraint and seclusion, health care workers can also be severely injured. Studies continually show that the occupation of mental health care worker is dangerous,⁶ with one study demonstrating that it can be more dangerous than that of construction workers.⁷ One study found that the largest percentage of patient assaults on staff members occurs during restraint or seclusion incidents,⁸ and another documented that most staff injuries are sustained when staff are trying to control patient violence.⁹

Full Extent of Deaths and Injuries Is Unknown Because Reporting to P&As Is Incomplete

The exact number of deaths each year in which restraint or seclusion was a factor is not known because reporting is fragmentary. We contacted the P&As for each state and the District of Columbia and asked them to identify people in treatment settings who died in fiscal year 1998 related to the use of restraint or seclusion. The P&As told us that restraint or seclusion was a factor in 24 of the deaths they reported in fiscal year 1998. But this number is likely to be understated, because P&A officials told us they do not learn

⁵Elaine Carmen, Bill Crane, Margaret Dunicliff, and others, Report of the Task Force on the Restraint and Seclusion of Persons Who Have Been Physically or Sexually Abused (Boston, Mass.: Massachusetts Department of Mental Health, Jan. 25, 1996).

⁶D.J. Drummond and others, "Hospital Violence Reduction Among High-Risk Patients," Journal of the American Medical Association, 261(17) (1989), pp. 2531-34.

⁷Jane A. Lipscomb, "Violence Toward Health Care Workers: An Emerging Occupational Hazard," American Association of Occupational Health Nurses, Inc. (AAOHN) Journal, 40(5) (May 1992), pp. 219-28.

⁸J.R. Lion and others, "Nursing Aides and Violence," American Journal of Psychiatry, 24 (1981), pp. 40-43.

⁹H. Carmel and M. Hunt, "Staff Injuries From Inpatient Violence," Hospital and Community Psychiatry, 40(1) (1989), pp. 41-46.

of all deaths that may be related to restraint or seclusion. Even though they are charged with the responsibility to protect the state's inpatient mentally ill population, only 15 of the 51 P&As receive any kind of systematic reporting of such deaths from their respective states or from psychiatric facilities. Of the 15, 9 receive death reports for state facilities only and not for private facilities.

Because of the lack of reporting requirements in most states, P&As learn about deaths on an ad hoc basis through complaints from family, patients, and staff, as well as through on-site monitoring. For example, the Texas P&A did not find out about one 1995 restraint-related death until 1998, when it was reported in a telephone call from a staff member at the facility. Even including these other methods, only 22 of these agencies had deaths reported to them by any means. Of the 1,203 deaths reported to the P&As in fiscal year 1998, over two-thirds were reported by just five states, and no deaths were reported to the P&As in 28 states. P&As investigated 376 of these 1,203 deaths. The P&A in New York—a state in which comprehensive reporting of such deaths is required—accounted for almost one-third of all the death investigations, while four other agencies investigated a combined 107 deaths.

Even if a P&A learns about a death, some P&A officials told us that it is often difficult to obtain incident reports and medical records to determine whether restraint or seclusion played a role in the patient's death. According to some P&A officials, health facilities often claim that these records are part of the peer review process¹⁰ and thus are protected from disclosure under state law. A major concern of many P&As we talked with was the need to litigate to obtain access to records that are critical for them to properly investigate a case. We were told that in some cases, litigation over access to records used up the agencies' limited resources, further delaying investigative efforts.

Many P&As indicated that they face even greater obstacles in obtaining information when the death occurred at a private facility. Obtaining information from private facilities is becoming increasingly important as more mental health patients leave state-operated facilities to receive residential treatment in other settings, which may include facilities

¹⁰The peer review process refers to the inquiry by a committee within the facility composed of medical personnel, which reviews incidents to determine how quality of care can be improved or whether professional standards were met. Most states have laws providing that the records of these committees are confidential and not accessible to parties who may want to sue the provider involved, but also providing that original documents cannot be protected just because they were considered by the peer review committee.

reimbursed through managed care. However, while many state agencies may gather data from their own state's facilities, private psychiatric facilities usually are not required to report data to either the states or the P&As. In 1984, 71 percent of the deaths reported in New York were in state facilities. In 1998, 78 percent of the reports came from private facilities. According to the New York State official in charge of investigations, this shift reflected, more than any other factor, a change in where individuals receiving treatment resided. New York is one of the few states that requires reporting of deaths from both public and private facilities. Without information from private facilities, this official said that the effectiveness of the state's reporting system would be severely limited.

In our survey, P&A officials told us that their ability to conduct investigations is also hindered by limited resources. Thus, even when they are aware of a death, it is possible that no investigation will take place because of a lack of funds or staff. For example, the Pennsylvania P&A officials stated that they limit their outreach efforts to the public hospital system because this system already provides more cases than they can handle. Many of the other P&As also noted that their representatives have only limited involvement with the private mental health system.

Federal and Other State Reporting Requirements Are Not Comprehensive

Federal reporting requirements differ by type of facility. On July 2, 1999, HCFA issued an interim final rule to revise the conditions of hospital participation in Medicare and Medicaid.¹¹ Effective August 2, 1999, it requires hospitals to report to HCFA deaths that occurred during—or can be reasonably assumed to be related to—restraint or seclusion. This regulation covers all hospitals but not other facilities that receive Medicare or Medicaid funds to provide treatment services to individuals with mental illness or mental retardation. ICF/MR and nursing home surveyors check and report to HCFA on use of restraints at the time of the facility's survey. Federal regulations now require hospitals to track and report on the use of restraint and seclusion. But there are no federal reporting requirements on restraint or seclusion use for other types of facilities. These facilities include community-based group homes and day treatment centers funded under the Medicaid waiver program and residential treatment centers for children. Yet, these settings are providing services to a growing number of individuals. Although federal regulations that implement the home and community-based waiver program do not specifically address reporting requirements for abuse and neglect (including the use of restraint and seclusion), states are required to make annual reports to HCFA on the

¹¹Federal Register, Vol. 64, No. 127, 36070 (July 2, 1999).

impact of their waiver programs on the health and welfare of the participants. HCFA is in the process of developing regulations that will address the use of restraint and seclusion in nonhospital settings that provide inpatient mental health services to children under the age of 21. These regulations are expected to include reporting requirements.

Most states do not comprehensively track either restraint use or related injuries. Further, JCAHO recently surveyed states regarding their requirements to report “sentinel events,” defined as unexpected occurrences involving death or serious physical or psychological injury, or the risk of such injury or death. While the results are preliminary, of the 34 states that responded to the JCAHO survey, only 16 and the District of Columbia indicated that they had a law that requires some type of sentinel event reporting to a state agency. Our study of the P&As found that only 11 states track restraint use in private psychiatric facilities.

The Center for Mental Health Services, within the Department of Health and Human Services’ (HHS) SAMHSA, has collected limited data on restraint and seclusion rates from five state psychiatric hospital systems as part of a study to determine the feasibility of tracking these and other performance measures. Though the data are not directly comparable among the five state hospital systems because of inconsistent definitions, it is clear that use of restraint and seclusion varies widely. For the five hospital systems, restraint use ranged from 0.6 to 48.1 episodes per 1,000 patient days, and the use of seclusion ranged from 0.2 to 29.1 episodes per 1,000 patient days. Likewise, data collected by New York State in its own review of its public psychiatric facilities in 1998 showed a wide range in restraint and seclusion use. Restraint use ranged from 0.01 to 4.7 episodes per 1,000 patient days, and seclusion use ranged from 0 to 8.76 episodes per 1,000 patient days.

**Accreditation Process
Relies on Voluntary
Reporting, Which Tends to
Be Incomplete**

Accreditation surveys are accepted by the federal government as proof that hospitals and psychiatric facilities meet requirements for participating in Medicare and Medicaid. While several agencies accredit providers of residential psychiatric care, JCAHO is the principal accrediting body for Medicare-certified hospitals, accrediting about 80 percent of these facilities. It also accredits many residential treatment facilities.

JCAHO does not require hospitals to report sentinel events—such as deaths related to restraint and seclusion. JCAHO’s sentinel event guidelines, issued in 1996, encourage voluntary reporting and encourage the hospital to

conduct a root cause analysis for quality improvement. If a hospital does not elect to report a sentinel event, JCAHO's expectation is that the hospital will still conduct a root cause analysis of the event for its internal use. If JCAHO finds out about a sentinel event that has not been reported, an accredited facility has 45 days to conduct a root cause analysis. JCAHO representatives said that the goal of this system is to be nonpunitive and to foster self-examination that can lead to quality improvement. The American Hospital Association, whose representatives said they believed mandatory reporting would encourage staff to cover up incidents, believes this is an effective approach.

JCAHO's policy requires hospitals to record restraint and seclusion use in patient records, which are subject to review during the accreditation process. However, the policy does not require hospitals to report these data, nor does JCAHO compile data on these rates. Twenty-one of the restraint- or seclusion-related deaths reported by the Hartford Courant occurred in JCAHO-accredited facilities since 1996, when its new sentinel event reporting system was established. Fifteen of these deaths were reported to JCAHO as sentinel events, three were not, and JCAHO did not have enough information to be certain about whether or not three others had been reported.

An additional problem with giving facilities choices about reporting is that it can limit the information available for independent review and lead to fewer cases being investigated. When New York first instituted a statewide reporting system, it allowed mental health facilities to decide whether a death was due to natural causes or unnatural causes, such as restraint or seclusion, and should be reported. In 1977, it reversed this decision and began requiring mental health facilities to report all deaths to the P&A. State officials said that this change was made because providers used their discretion under the former policy to decide that deaths were the result of some other cause, even if the patient had been restrained or secluded during the incident. New York shifted the determination of which deaths were related to seclusion and restraint to the P&A because of concern that hospitals have a tendency to underreport suspicious deaths.

Policies Governing Restraint and Seclusion Use Vary Among Programs, States, and Facilities

Policies covering the use of restraint and seclusion vary among federal programs, states, and types of facilities. Until recently, individuals had federal regulatory protection against improper restraint and seclusion only if they resided in nursing homes or ICF/MRS. Effective in August 1999, HCFA incorporated into the hospital conditions of participation patient rights provisions, which address restraint and seclusion. In addition, states are required to ensure the health and welfare of home and community-based waiver participants. However, current regulations do not protect people receiving psychiatric care at nonhospital providers such as residential treatment centers, day treatment centers, and group homes. States have varying degrees of regulatory protection for people receiving care in residential settings, but sometimes those regulations cover only state-run facilities. JCAHO addresses restraint and seclusion in its accreditation process. While hospital industry spokespersons see accreditation as an effective means of ensuring appropriate use of restraint and seclusion, many patient advocates are concerned that the accreditation process alone does not sufficiently protect individuals in treatment settings.

Federal Requirements Do Not Address Restraint and Seclusion Use for All Providers

Federal regulations governing two types of facilities establish affirmative rights for individuals to be free from restraint—except under specific circumstances—and seclusion. Residents in long-term-care facilities that participate in Medicare or Medicaid have the right to be “free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms,” and may not be placed in seclusion. ICF/MRS must “ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints.” The ICF/MR regulations specify that restraint may be employed only as part of an individual behavioral teaching program, as an emergency measure when necessary to protect the individual or others from injury, or to facilitate medical treatment.

Federal requirements for Medicaid home and community-based waiver programs do not specifically address restraint or seclusion, but do require that the state applying for the waiver provide satisfactory assurances that necessary safeguards are in place to protect the health and welfare of the recipients of the services. States must adopt standards to meet the safeguard requirement that reflect each state’s approach to ensuring quality care and safety for the program participants. These standards may include professional licensing standards, certification for group homes, and local building and safety codes.

As mentioned earlier, HCFA recently added federal guidelines on restraint and seclusion use for hospitals, including psychiatric hospitals. On July 2, 1999, HCFA published its interim final rule with revised conditions of participation for hospitals, effective on August 2, 1999. These conditions will also apply to psychiatric hospitals, because psychiatric hospitals that participate in Medicare must meet the same conditions of participation all hospitals must meet, along with two additional conditions addressing medical records and staffing. The interim final rule establishes the right for patients to be free from restraint or seclusion as a means of coercion, discipline, or staff convenience. These measures may be used only for medical or surgical care or in emergency situations to ensure the patient's physical safety and after less restrictive interventions have been found ineffective to protect the patient or others from harm.

HCFA is currently reviewing whether the revised conditions of participation should apply to residential treatment centers for children. These providers are rapidly replacing hospitals in treating children with psychiatric disorders and are a less restrictive alternative to a hospital for children whose illness is less acute but who still require a therapeutic residential environment. All providers who receive Medicaid funding to treat such children must provide "active treatment" according to a plan of care developed by an interdisciplinary professional team. HCFA issued proposed regulations in 1994 with conditions of participation for residential treatment centers, but these regulations have not been finalized.

Degree of Patient Protection Varies Among States

States have varying degrees of regulation and oversight for restraint and seclusion. They set licensing standards, survey facilities for compliance with the standards, contract with private providers for state-funded services, and provide care directly in state-run facilities. Some states have different standards for their state-run facilities than for private providers. Private psychiatric hospitals are frequently not subject to the same degree of oversight as the state-run facilities. Even some states with extensive regulation of their public hospitals—such as Pennsylvania and New York—have not imposed the same requirements on the private sector.

Individuals with mental illness or mental retardation residing in state-operated facilities have certain basic rights that have been recognized by federal courts. In a case involving a man with mental retardation confined to a Pennsylvania state institution, the U.S. Supreme Court held that institutionalized people have constitutionally protected

rights to safety and freedom from undue bodily restraint.¹² In determining whether restraint is reasonable, the Court indicated that the proper inquiry is whether professional judgment was exercised when the restraint was ordered. Further, a federal district court issued detailed standards to address conditions in three Alabama state treatment facilities.¹³ These include the requirement that written orders for restraint or seclusion be prepared by a physician or qualified health care professional after evaluating the individual in treatment and are valid only for 24 hours. Emergency imposition of restraint or seclusion in the absence of a written order may last only an hour. People in restraint or seclusion must have their physical and psychiatric conditions assessed hourly and must be allowed to use the bathroom every hour. Some states have chosen to incorporate the principles of this case into their own laws, which often vary as to the type of professional who is authorized to order an emergency restraint, the maximum length of time orders are valid, and the frequency of required monitoring.

Accreditation Process Lacks Specifics

The accreditation process plays an important role in promoting industry standards and quality improvement. However, representatives of health care providers and family advocates differed about whether the accreditation process alone is sufficient to protect patients.

JCAHO, which accredits about 80 percent of the hospitals that participate in Medicare, has developed standards on the appropriate use of restraint or seclusion. JCAHO applies the same standards for the use of restraint and seclusion to both hospitals and nonhospital behavioral health care treatment facilities. As part of the accreditation survey, JCAHO surveyors conduct record reviews to determine whether restraint or seclusion are used and documented according to its standards and facility policy. Routine JCAHO surveys are conducted every 3 years. JCAHO conducts random, unannounced surveys on 5 percent of its accredited providers and infrequently conducts unannounced surveys for cause. JCAHO reports that since adopting its current policy on voluntary reporting of sentinel events, it has received reports of 24 restraint-related deaths in facilities it has accredited. On the basis of these reports, it published a Sentinel Event Alert in November 1998 with its summary of the root cause analyses of 20 restraint-related deaths from its sentinel event database.

¹²Youngberg v. Romeo, 457 U.S. 307 (1982).

¹³Wyatt v. Stickney, 344 F. Supp. 373 (M.D. Ala., 1973).

Representatives of health care provider organizations told us that the accreditation process is the most appropriate way to ensure that patients are protected from the improper use of restraint and seclusion. They believe that a voluntary review process that does not involve mandatory disclosure allows the facility to address any systemic clinical problems and develop quality improvement plans for the future. For that reason, they believed that additional regulation is not needed.

In contrast, many advocates are concerned that the accreditation process is not sufficient to establish consistent patient protection. Although JCAHO surveyors tour facilities and talk with patients and staff to better understand care issues at a facility, advocates noted that the overall process emphasizes paperwork reviews, which can miss ongoing quality-of-care problems.

States Have Lowered Restraint and Seclusion Use Through Regulation, Reporting, Training, and Staffing

Several states have lowered restraint and seclusion use in their public psychiatric health systems and have instituted reporting requirements. Providers, advocates, and state officials indicated that management commitment to patient protection, regulation, reporting, and monitoring have led to increased patient and employee safety. However, they believe a program to reduce restraint rates also requires effective training programs for staff, adequate staffing, and independent oversight.

State Regulation and Reporting Have Led to Less Use of Restraint

In the last several years, Delaware, Massachusetts, New York, and Pennsylvania have adopted strategies to reduce restraint use in their public mental health or mental retardation service systems. The officials we met with at the state health departments indicated that the primary reason for their success in reducing restraint use is management commitment to achieving this goal. Management philosophy, not patient acuity, was the most important factor in determining restraint use at different state hospitals, according to a 1994 study conducted by the New York Commission on Quality of Care.¹⁴ Management can take responsibility for shaping the overall culture in which restraint and seclusion are either considered routine practice or last-resort measures. An integral part of this commitment is a clearly delineated set of policies and procedures for staff to follow governing the use of restraint and seclusion.

¹⁴New York State Commission on Quality of Care for the Mentally Disabled, Restraint and Seclusion Practices in New York State Psychiatric Facilities (Albany, N.Y.: 1994).

For example, in Pennsylvania, the deputy secretary for mental health emphasized to all hospital administrators and staff that restraint and seclusion are not treatment but rather represent an emergency response to a treatment failure that resulted in an individual's loss of control. The state Department of Mental Health issued policies specifying that restraint or seclusion may be used only after all other interventions have failed and when there is imminent danger of physical harm to the individual or others. A physician must make an on-site assessment within 30 minutes. According to state officials, despite initial opposition to these restrictions within the facilities, the Department's emphasis on maintaining adequate staffing levels and improving crisis management training allowed it to gain the support of psychiatrists and direct care workers. Pennsylvania, which administers a system of 10 facilities with over 3,000 individuals with psychiatric problems in residence, was able to reduce both restraint and seclusion hours by over 90 percent between 1993 and 1999.

Reporting requirements play a central role in lowering restraint use and improving safety for people in treatment settings. Officials in New York and Pennsylvania stated that accurate and complete reporting allows hospital administrators to compare their facilities with others and focus on quality improvement within their facilities. This creates an incentive for administrators with high restraint rates to find ways to reduce them so they are more in line with their peers. A 1999 survey by the National Association of State Mental Health Program Directors indicated that 18 states currently require reporting on restraint and/or seclusion use in their public hospitals.

In addition to tracking restraint rates, reporting of deaths or other sentinel events to an independent agency can contribute to improved safety for people in treatment settings. New York is unique among states in its long-standing comprehensive reporting requirement. All licensed hospitals that provide inpatient psychiatric care must report all deaths to the Commission on Quality of Care as well as the relevant state agency and indicate whether the individual had been restrained or secluded within 24 hours of death. Mandatory reporting and investigation allow an independent entity to analyze events at multiple facilities. Because the Commission and other agencies review information from the entire state, they can determine whether incidents that appear to be isolated events from the perspective of individual providers are actually part of a pattern. For example, comprehensive incident reviews led to the discovery that two authorized restraints—the prone wrap-up and the use of a towel to prevent biting or spitting—were associated with injuries and deaths

throughout the state.¹⁵ As a result of these analyses, these two types of restraint were banned.

Some industry and physician representatives have expressed concern that mandatory reporting requirements could thwart provider efforts to gather information and analyze adverse outcomes. Their concern is that mandatory reporting to an independent body will make employees more likely to cover up their mistakes. This, in turn, would limit a hospital's ability to gather all the facts it needs to identify weaknesses that can be changed to improve care for future patients. However, according to a hospital industry representative in New York, hospitals have not found this to occur in response to the state's mandatory reporting requirement. In fact, according to this official, the requirement has been in place so long now that hospitals have accepted it as a normal part of doing business.

Another concern cited by providers relates to the increased administrative burden associated with a new reporting requirement. However, all JCAHO-accredited facilities already must document restraint or seclusion use in patient records. In addition, both public and private providers are currently developing performance measures to better track quality of care.

Restraint and seclusion use is one measure being tested by both the public and the private sector to determine behavioral health care quality. The main public sector effort consists of a multiphase feasibility study by HHS' Center for Mental Health Services. It began by assessing five states' capacity to measure numerous demographic and quality indicators within their state-run psychiatric systems and is expanding to 16 states. On the private sector side, JCAHO has initiated a major data compilation system—ORYX—which will ultimately include all accredited facilities. The goal of both these projects is to help facilities improve care by tracking performance measures and be able to evaluate their own performance over time, as well as compare themselves with similar facilities. Although both systems include restraint and seclusion use, not all hospitals participating in ORYX have opted to track this measure.

¹⁵The use of a towel had been authorized by certain hospitals as a precaution against biting and spitting during take-down and restraint to protect staff against possible infection. On banning the use of this procedure, the Commission indicated that no objects should ever be placed over or near a patient's face because of the danger of asphyxiation and recommended that staff wear gloves and masks and, if necessary, wrap the patient in a "calming blanket" as a safe barrier. The prone wrap-up consisted of immobilizing a person in a face-down position.

Training and Adequate Staff Ratios Help Decrease Restraint and Seclusion Use

Clinicians, advocates, labor unions representing mental health workers, program administrators, and providers consistently stress that training and adequate staff-to-patient ratios are essential to safely minimize use of restraint and seclusion. To safely use restraint or seclusion when there is no other option, staff need training in how to put individuals in and take them out of restraint. This would include training in monitoring a restrained individual's physical condition. To reduce restraint and seclusion use, nurses and other direct-care staff need to have effective alternative methods for handling potentially violent individuals. In the states we visited, training programs that address how to handle potentially violent or aggressive individuals were an integral part of the effort to safely reduce reliance on restraint and seclusion. In its interim final rule implementing new hospital conditions for participation in Medicare and Medicaid, HCFA has added requirements that hospitals train their staffs in alternative techniques to lessen reliance on the use of restraint and seclusion, but these requirements do not extend to residential treatment centers or group homes.

New York, Massachusetts, Delaware, and Pennsylvania initiated training programs that emphasize crisis prevention. The goal of the training was to give staff the skills to assess potentially violent situations and intervene early to help individuals regain control. State officials as well as labor union representatives stressed that direct-care staff must be trained in alternative techniques if a facility is serious about reducing restraint and seclusion. Federal officials emphasized that training should differentiate between techniques suitable for children and those for adults.

Officials at Delaware's ICF/MR told us that staff and patient injuries decreased after staff had been trained in alternate ways of managing patient behavior. According to a patient advocate, Delaware's emphasis on reducing restraint rates was precipitated by a 1994 restraint-related death in the state ICF/MR. Following implementation of a new training program that emphasized training in crisis prevention and new priorities by management, this facility reduced the number of emergency restrictive procedures by 81 percent between 1994 and 1997, with the number of procedures per resident falling from 1.38 to .29 during that time. Along with this reduction in restraint, the number of major injuries to residents fell by 78 percent and resident behavior improved. A psychologist from Delaware's ICF/MR noted that once staff have experienced success in calming a resident through alternate means when restraint would have otherwise been used, the new techniques become self-reinforcing because staff prefer to use less drastic measures.

The mental health program officials we met with indicated that training in alternatives to restraint and seclusion and maintaining adequate staff levels are costly, but they can save money in the long run by creating a safer treatment and work environment. Data from state hospitals in New York indicated that usually facilities with higher restraint and seclusion rates had higher rates of staff injury and lost staff time. A New York State official noted that many of the injuries classified as assaults actually took place during restraint and seclusion procedures. Staff training has been found to save the state money by directly reducing the frequency of restraint-related staff injuries, which represent costs of sick leave and overtime payments for staff to cover the shifts.

Independent Oversight and Investigation Contribute to Patient Safety

Advocates and state administrators we interviewed often expressed the view that the most effective monitoring system involves a combination of internal and external oversight. Medicare and Medicaid generally require providers to have internal quality-of-care monitoring and assessment programs. JCAHO requires accredited facilities to have quality improvement processes and to investigate the causes of sentinel events internally. HHS' Office of Inspector General recently reported that the most effective system involves a balanced combination of peer review to emphasize quality improvement and independent regulatory oversight to ensure compliance with basic patient safety standards.¹⁶

External monitors complement internal quality control systems by providing an independent perspective. In addition to accreditation or state licensing surveyors and P&As, some states allow trained lay monitors to visit mental health facilities unannounced and assess environmental conditions. In Delaware, for example, if a monitor reports a concern about conditions in the state psychiatric hospital, the facility must respond within 10 days. Because staff at the facilities know the reports are reviewed and acted on by management, they sometimes inform monitors about concerns that affect patient care, such as low staffing. In some cases, courts have appointed independent monitors to ensure compliance with specific requirements and safeguarding of basic patient rights in facilities that have had serious problems.

Investigations into specific events may be conducted by each facility, by a peer review committee, state or federal authorities, law enforcement agencies, or the P&As. Some P&A directors believe the outside review of

¹⁶HHS Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability* (Washington, D.C.: HHS, July 20, 1999).

state mental health systems is necessary to ensure an objective look at problems within state-operated facilities. In Massachusetts, investigators informed us that the peer review process and official investigations occur independently. However, many P&As from other states indicated that their investigations are hampered when providers seek to preclude access to all documents under review by the peer review committee. The degree to which P&A agencies can investigate deaths or injuries also depends on each agency's priorities, relationship with the state government, and resources. The New York P&A is a state agency that operates independently to review all deaths and conduct investigations. In Massachusetts, the P&A lacks sufficient staff to conduct individual death investigations, but it receives reports of all deaths and monitors the state agencies to ensure that they investigate incidents satisfactorily. The Massachusetts P&A staff indicated that the state system incorporates sufficient "checks and balances" to ensure independent review of both state-operated and private providers.

Conclusions

People with mental illness or mental retardation in residential settings are among the most vulnerable members of our society. Protecting them from abuse and injury is a responsibility of the federal government, the states, the treatment facilities, and the P&A system. However, the safeguards currently in place are not comprehensive and fail to fully ensure the rights and safety of these individuals.

The use of restraint and seclusion represents a significant risk to such individuals, but without more comprehensive reporting to a state licensing body, P&A, or the federal government, the total number of injuries and deaths each year will not be known. Because few states require comprehensive reporting of such events to P&As, we believe that many more deaths occur than those reported to the P&As. Although P&As are charged with the responsibility to help protect people with mental illness and mental retardation, in some states they lack the information and resources to do so.

The federal government does not have consistent requirements on reporting such injuries and deaths of patients. HCFA's implementation of the new conditions of participation for Medicare and Medicaid hospitals includes a reporting requirement on deaths related to restraint or seclusion. However, this requirement does not apply to all Medicare- and Medicaid-funded facilities that serve people with mental illness and mental retardation. Reporting injuries and deaths allows authorities to comprehensively review patterns and identify particularly dangerous

practices, and thus it is an important step in reducing such incidents and improving safety. This can complement a facility's own efforts to analyze a sentinel event and change its policies and procedures to prevent the occurrence of similar deaths or injuries in the future.

The experience of several states shows that use of restraint and seclusion can be reduced and that people receiving treatment and staff are safer as a result. Successful strategies such as clear guidelines and a comprehensive reporting requirement; commitment by management; adequate staffing levels; and staff training in the safe use of, and alternatives to, restraint and seclusion are key. Among the new conditions of participation for Medicare hospitals, HCFA's requirement that hospitals train their staff in alternatives to restraint and seclusion is a step in the right direction.

In addition to not consistently requiring reporting, the federal government has not implemented consistent policies on the use of restraint and seclusion for Medicare- and Medicaid-reimbursed facilities. As a result, protections against the improper use of restraint and seclusion vary widely depending on the program and facility. While patient protections are now included in federal regulations governing hospitals, nursing homes, and ICF/MRS, a significant and growing number of individuals living in other residential settings such as residential treatment centers and group homes lack such safeguards. Although state regulations may offer some protections, this protection is still not consistent among all individuals whose treatment is funded through either Medicare or Medicaid. We believe that HCFA's new conditions of participation for Medicare hospitals is a positive action, but it does not fully protect all people with mental illness and mental retardation served by the Medicare and Medicaid programs.

Recommendations

We recommend that the HCFA Administrator ensure that protections regarding the use of restraint and seclusion are consistent by extending to all individuals receiving treatment in Medicare- and Medicaid-funded facilities, including those in facilities covered under a waiver program, protections such as those currently in place for these individuals in hospitals, nursing homes, and ICF/MRS. These protections include a right to be free from any physical or chemical restraints or seclusion imposed for the purposes of coercion, discipline, or staff convenience and to receive active treatment to reduce dependency on chemical or physical restraint or seclusion. Restraint or seclusion would be used only for medical or surgical care, as part of an individual behavioral teaching program that is

intended to lead to a less restrictive means of managing and eliminating the behavior for which the restraint is applied, or in emergency situations when necessary to ensure the individual's or others' physical safety and after less restrictive interventions have been ineffective to protect the individual or others from harm.

We also recommend that the HCFA Administrator mandate that any hospital or residential facility that treats individuals with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds,

- using a uniform reporting protocol, report promptly to the state licensing body and the appropriate P&A all deaths and serious injuries among individuals with mental illness or mental retardation to facilitate effective investigation, and indicate whether restraint or seclusion was used during or immediately before death or injury;
- maintain records to document the facility's use of restraint and seclusion and report rates of use to HCFA periodically, using common definitions; and
- ensure that staff regularly receive training and refresher courses in safe methods to handle agitated or potentially violent individuals, including alternative methods to restraint or seclusion, and document staffs' receipt of the training.

Agency Comments and Our Evaluation

We provided draft copies of this report to HHS, two of its agencies—HCFA and SAMHSA—and JCAHO for comment. SAMHSA and JCAHO officials provided oral comments, and HCFA officials provided written comments (see app.) HHS was unable to provide written comments in time to be included in the report. The reviewing officials also suggested some technical corrections, which we incorporated in the report where appropriate.

Generally, HCFA agreed with the report's contents and concurred with our recommendations. HCFA stated that it believed people should be free from inappropriate use of restraint and seclusion when receiving care. In response to our recommendations, HCFA detailed the steps it has taken and plans to take to improve the quality of care. Chief among the actions cited was HCFA's recent interim final rule establishing new conditions of participation for hospitals. In addition, HCFA referred to its collaborative work with HHS' Office of Inspector General and its intent to work with others such as state agencies, JCAHO, and SAMHSA to further ensure patient safety in other treatment settings.

Regarding our recommendation that patient protections should apply to individuals with mental illness and mental retardation in all Medicare- and Medicaid-funded facilities, HCFA stated that it is studying the advisability of applying the restraint and seclusion standards in the new conditions of participation for hospitals to other providers. However, HCFA cautioned that implementation of these protections must be tailored to the specific treatment setting in question. While we agree that HCFA may need to take into account differences among treatment programs in establishing patient protections, we believe that HCFA should take action to ensure the safety of all individuals with mental illness and mental retardation, regardless of the setting in which they receive treatment.

In response to our recommendation that all deaths and serious injuries be reported to an outside agency, HCFA cited its new conditions of participation for hospitals, which require reporting of a death if the death is due to restraint or seclusion. However, we note that the experience of New York State suggests that if facilities are given the option of determining whether a death is related to restraint or seclusion, they do not always report all deaths that might be related. We believe it is important to report all deaths and serious injuries of people in restraint or seclusion in order to allow an independent monitor to determine whether the death or injury was related to restraint or seclusion.

We had suggested that HCFA maintain a database on rates of restraint and seclusion by facility. In response, HCFA noted that it is planning to work with the Food and Drug Administration and SAMHSA to determine the best way to implement this record keeping. We consider this interagency coordination to be an appropriate approach for HCFA to use and therefore removed the suggestion that HCFA maintain the database. However, we believe it is important that one of these agencies maintains such data. Finally, HCFA agreed with our recommendation on staff training, emphasizing that it has such a provision now for hospitals and nursing homes. HCFA said it will examine requirements for state Medicaid agencies to ensure that similar training requirements are in place for staff in treatment facilities paid under Medicaid's home and community-based waiver.

SAMHSA officials generally agreed with the report's contents. The officials agreed with the need for a comprehensive reporting system. HCFA has indicated its intent to work with SAMHSA and others to develop an appropriate reporting mechanism. SAMHSA officials also suggested that they would work with HCFA and others to identify and communicate best

practices for facilities and providers to use to avoid the use of restraint and seclusion.

SAMHSA officials also said that, given the P&As' current lack of resources, if additional duties are imposed on them, they will require increased funding from the Congress. We highlighted the lack of resources of the P&As in the report and believe that additional responsibilities without commensurate resources would not result in improved patient protection.

JCAHO officials emphasized that reporting sentinel events was only a first step in preventing deaths and injuries. For reporting to have any effect, it has to be paired with an in-depth analysis of the root cause that led to the death or injury, followed by procedures and practices to reduce risk in the future. JCAHO officials emphasized that their approach—voluntary reporting with root cause analysis—promoted a culture in both inpatient and residential settings that was conducive to quality improvements. In JCAHO's opinion, mandatory reporting would not be an effective solution unless it was accompanied by requirements for a root cause analysis and corrective action. Furthermore, JCAHO believes that requirements for mandatory reporting should include safeguards so that facilities would not lose current state protections against disclosure of peer review results. We agree that reporting is only part of a successful strategy to lower restraint and seclusion use, as evidenced by the experiences of the states we visited. States such as Pennsylvania and New York have used mandatory reporting to help lower restraint use in their state hospital systems.

JCAHO officials also emphasized that their organization has worked to develop standards relating to restraint and seclusion use for facilities JCAHO accredits. One of JCAHO's goals in recent years has been to lower the use of restraint and seclusion. According to these officials, JCAHO's standards have served as a model for others, including protections in the new interim final rule for hospitals. Furthermore, in response to advocates' criticism of JCAHO's survey process, the officials stated that surveys have changed in recent years to a more in-depth evaluation of a facility's operational compliance with JCAHO accreditation standards, including standards that relate to restraint or seclusion.

JCAHO officials also stressed that restraint and seclusion are dangerous to both staff members and individuals being treated. They stated that while staff training in alternative techniques to avoid restraint use was important, staff should also be trained in the proper application and removal of restraints and in how to monitor individuals in restraint or

seclusion. We agree that staff training is a crucial element not only in reducing the use of restraint or seclusion but also in ensuring the proper use of these techniques.

As agreed with your offices, unless you release its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will make copies available to other congressional committees and Members of the Congress with an interest in these matters; the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Nancy-Ann Min DeParle, Administrator of HCFA; and Bernard Arons, M.D., Director of the Center for Mental Health Services, SAMHSA.

This report was prepared by Frank Putallaz, Suzanne Rubins, and Sondra Schwartz under the direction of Sheila Avruch, Assistant Director. Please call William J. Scanlon, Director, Health Financing and Public Health Issues, at (202) 512-7114, or me at (312) 220-7600 if you or your staffs have any questions about this information.



Leslie G. Aronovitz
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Comments From the Health Care Financing Administration



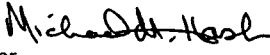
DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

AUG 11 1999

TO: Leslie Aronovitz, Associate Director
Health Financing and Public Health Issues,
General Accounting Office

FROM: Michael M. Hash 
Deputy Administrator,
Health Care Financing Administration

SUBJECT: General Accounting Office (GAO) Draft Report, "Mental Health: Improper Use of Restraint or Seclusion Places Patients At Risk."

We appreciate the opportunity for the Health Care Financing Administration (HCFA) to comment on the report, "Mental Health: Improper Use of Restraint and Seclusion Places Patients at Risk". We welcome this General Accounting Office report because we fully believe that people should be free from the inappropriate use of seclusion and restraints when receiving care.

Overview

The report underscores the importance of steps we are taking to improve the quality of care delivered to people with mental illness. It will be helpful as we take additional action to protect the health and welfare of Americans, including persons with mental illness in hospitals. We are implementing several initiatives, including those suggested by the General Accounting Office for hospitals to improve the quality of care in various health care settings. Our regulations to ensure the appropriate use of restraints and seclusion and our action plan to improve the hospital accreditation process are important milestones in our continuing commitment to protect the health and safety of all people.

HCFA is also seeking the commitment of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to improve its performance in monitoring hospitals for any deaths or sentinel events associated with the use of restraints. We achieved one of the goals articulated in our accreditation action plan on August 4 when the Joint Commission announced that hospitals will no longer receive notices of random surveys.

Hospitals

Because of the importance of the restraints issue to the health and safety of patients in hospitals, HCFA "carved out" the patients rights' section, which addresses the seclusion/restraint issues, from the larger hospital Conditions of Participation regulations. These patients' rights regulations

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will strengthen existing protections of patient health and safety and will assure that high quality care is provided to all patients in hospitals participating in the Medicare and Medicaid programs. The six basic rights specified in the regulations include the right to confidentiality of patient records and communications, and the freedom from the inappropriate use of restraints and seclusion.

By putting these protections on a separate track, HCFA was 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 patients' rights protections were issued as interim final regulations on July 2. The new protections were effective August 2. They make hospitals, including acute, psychiatric, rehabilitation, long-term, children's and alcohol-drug hospitals, subject to sanctions if the new Conditions of Participation are not met.

The newly effective patient protection regulations require that a hospital provide a patient or family member with a formal notice of their rights at the time of admission. These rights include the right to be free from restraints and seclusion in any form when used as a means of coercion, discipline, convenience or retaliation. Other rights include the right to privacy and confidentiality and the right to make decisions about the patient's care.

If patients and their families have any concerns about the quality of care provided at a hospital, they may contact the state survey agency or HCFA regional office to find out whether the hospital had been cited for a violation of the patient safety protections.

HCFA's regulations also contain new requirements on staff training so that health care workers who have direct patient contact will learn the appropriate and safe use of seclusion and restraints. The new patient protections also make consistent standards used by HCFA and the JCAHO to ensure only appropriate use of restraints and seclusion. HCFA adopted the same approach and time frames for monitoring the use of restraints and seclusion developed and enforced by the Joint Commission when it accredits hospitals and behavioral health facilities.

Long Term Care

HCFA has previously issued regulations that require the appropriate use of restraints in intermediate care facilities for the mentally retarded (ICFs-MR) and nursing facilities. The Clinton Administration has made improving the quality of nursing home care a top priority. In July 1998, the President announced a broad initiative to strengthen the oversight of our nursing home regulations which were published in 1995.

Residential Treatment Facilities

HCFA plans to work closely with States, Congress, and patients' rights advocates to expand the scope of our patients' rights policy to health care settings where HCFA does not now have regulations in place, such as residential treatment centers for children and congregate care

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services. Current regulations apply only to hospitals that participate in Medicare and Medicaid, nursing homes and ICFs-MR.

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

HCFA is also collaborating with the HHS Office of Inspector General (OIG) to obtain more information about existing patient abuse reporting systems and oversight of psychiatric hospitals. The OIG is currently conducting three studies to provide policy makers with up-to-date information about these issues.

GAO Recommendations

The following is HCFA's response to the GAO's four recommendations for Medicare/Medicaid approved hospitals, long term care facilities (LTC), and intermediate care facilities for the mentally retarded (ICF/MR), as well as residential treatment facilities such as inpatient psychiatric services for individuals under age 21 (Psych under 21), and home and community based services (HCBS) waiver programs:

Recommendation #1: The report recommends that the HCFA Administrator ensure that patient protections regarding the use of seclusion and restraints are consistent by extending to all Medicare and Medicaid mentally ill or mentally retarded patients, including those in facilities covered under waiver programs, protections such as those currently in place for such patients in hospitals, nursing homes, and ICF/MRs.

Response: The patients' rights section of the hospital Condition of Participation (CoP), published July 2, 1999 and effective on August 2, 1999 was an important accomplishment in addressing the recommendation to ensure that hospitalized patients are protected from the use of seclusion and restraints.

The 1990 nursing home regulations promulgated in response to the reform provisions of OBRA 87 provide for patient protections from inappropriate use of chemical and physical restraints, which includes seclusion. Under these requirements all nursing home residents have the right to be free from any physical or chemical restraints imposed for the purpose of discipline or convenience, and not required to treat the resident's medical symptoms. In implementing these regulations, HCFA has worked closely with consumers, professional provider and State agency groups to develop extensive guidance on how to interpret and enforce these provisions,

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sponsored frequent training programs throughout the nation on appropriate restraint reduction approaches, and emphasized the assessment of restraint use as a critical part of the survey process. This major national initiative has contributed to the significant reduction that has occurred in the restraint use in nursing homes over the last 9 years.

In Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) regulations were published in 1988 that require that restraints be used only as an integral part of an individual program plan that is intended to lead to a less restrictive means of managing and eliminating the behavior for which the restraint is applied. Restraint should be used only if the danger of the behavior outweighs the danger of the use of the intervention. HCFA has sponsored training for surveyors and facilities on the appropriate and inappropriate use of restraints in ICFs/MR. HCFA will continue efforts to assure that inappropriate restraint and seclusion use is not taking place in ICFs/MR.

In the Hospital Conditions of Participation regulation referenced earlier, we stated that we are studying the advisability of adopting cross-cutting seclusion and restraints standards that would affect other providers that receive Medicare and Medicaid funding. HCFA specifically requested comments on whether we should adopt the same requirements as promulgated in the rule for hospitals or different standards for other providers. HCFA requested comments on the feasibility of adopting the same requirements for residential treatment facilities that provide inpatient psychiatric services to individuals under age 21, or whether different specialized standards are needed in these facilities. HCFA is identifying the issues that need to be addressed in designing and developing standards that are responsive to the concerns of those submitting comments, and place the health and safety of individuals served in these facilities at the center of the design process. HCFA has committed to work to extend protections to residential care facilities for children and other providers participating in the Medicaid program by the end of this year.

The protections included in the Hospital CoP regulation are specific to the demands of furnishing services in the institution (i.e., the hospital). They relate to the operation of the institution and how it provides care to its patients, rather than to the individuals who receive their care in the institution. These protections could not be readily replicated in the *non-institutional* arena of the HCBS waiver. We believe, however, that there are certain key components which may be common to a system that prohibits abuse, mistreatment, and neglect. Preventing incidents of abuse is basic to providing care in any service setting regardless of provider type or population served. HCFA is aware that the use of restraints and seclusion increases the potential for injury and abuse, and that patient protections are needed in all residential settings. However, since we share oversight responsibility for congregate care settings with the States, we need to develop protections that can be effectively monitored by this system that is significantly different from hospital oversight and enforcement.

Recommendation #2: The report recommends that the HCFA Administrator require that any inpatient or residential facility that treats individuals with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds, report promptly to the state licensing

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body and the appropriate protection and advocacy agency (P&A), all patient deaths and serious injuries to facilitate effective investigation, and use a uniform reporting protocol indicating if seclusion or restraint were used during or immediately prior to the death or injury.

Response: In the new Patients' Rights CoP for hospitals, hospitals must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is result of restraint or seclusion. In the comment period which closes September 2, 1999, HCFA solicited comments on reporting injuries, realizing that defining the term "serious injury" is very challenging. Hospitals are to report deaths due to seclusion or restraints to HCFA's Regional Offices (RO) and this information will be reported by the RO to the Protection and Advocacy Agencies using a standardized report. Currently HCFA is working with States and survey agencies to develop this standardized report. Based on the comments we receive about the utility of reporting injuries, HCFA will evaluate whether injuries must be reported by hospitals as well as other facilities.

Since 1990, nursing homes have been required to report all alleged violations and resulting investigations involving mistreatment, neglect, or abuse including injuries of unknown source and misappropriation of resident property to officials in accordance with State law and to the State survey agency. HCFA will assess comments made on the new hospital regulation to determine if modifications to the nursing home reporting requirement are necessary.

The regulations for ICFs/MR already require the reporting of all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source. These are to be reported immediately to officials in accordance with State law and through established procedures. HCFA guidelines also outline several very specific requirements regarding investigation, protection of the individuals during the investigation and needed actions.

Currently, inpatient psychiatric services for children (psych under 21) may be provided in residential treatment facilities that are accredited by the Joint Commission, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or any other accrediting body with comparable standards that is recognized by the State. We are reevaluating our expectations and the requirements for State Medicaid agencies to oversee the provision of this service and to protect the health and safety of individuals in facilities that provide this benefit.

HCBS waivers permit States to furnish services as an alternative to care in an institutional setting. States use waivers to furnish services in private homes and apartments, day settings as well as group homes and other congregate living arrangements. Identification and implementation of rules or protocols for reporting deaths and serious injuries varies significantly across the States.

In recent years, more and more States have been serving an increasing number of beneficiaries with mental illness in the community rather than in institutions. Under community-based programs, we are committed to striking the right balance between ensuring adequate beneficiary

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protections and fostering beneficiary independence and self-determination. In partnership with States, we are examining safeguards that could be put in place for services furnished by the different types of providers of community-based services with a focus on the safety and well-being of our beneficiaries. We are also developing an outreach strategy to ensure the advocacy community has a strong voice in these important discussions. In addition, we are beginning the initial steps to identify state innovative practices for quality assurance mechanisms for home and community-based services and initiating developmental efforts to enhance performance management, such as consumer surveys and performance measurement for chronically ill individuals.

Recommendation #3: The report recommends that the HCFA Administrator require that any inpatient or residential facility that treats individuals with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds, maintains records to document the utilization of restraints and seclusion and mandate that these be reported to HCFA periodically by the facility, using common definitions, for maintenance in a database.

Response: We agree such information would be useful. HCFA will work with FDA and SAMSHA to determine whether existing databases meet this need, or whether a separate and distinct database within HCFA is needed. We must also consider how hospitals could collect and report this information in an effective and efficient manner. Additionally, this data collection activity would duplicate the efforts of federal and state organizations like the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the State Protection and Advocacy (P&A) Systems. The FDA receives information on problems or deaths related to restraints since certain types of restraints are considered medical devices, and SAMHSA works closely with the State P&A Systems and has access to such data. Both SAMHSA and the State P&A systems presently monitor issues related to mental health, restraints and seclusion. We have solicited comments on such a database in the hospital CoP, Patient's Rights rule, and are looking forward to the public's comments on this recommendation. In the meantime, HCFA will explore with the FDA and SAMHSA whether the existing databases are adequate (comprehensive, reliable, and valid) for this purpose and whether the databases would be accessible to HCFA and the State survey agencies for survey activities.

HCFA collects information about the use of restraints in nursing homes through the minimum data set (MDS) submissions and a facility completed form on resident characteristics collected at the annual standard survey. The MDS must be completed periodically by the facility for each patient and submitted to HCFA. The MDS includes items on restraint use. HCFA also collects data from the facility on the number of residents in restraints at the time of each survey. Therefore, HCFA and state survey agencies have detailed information on the characteristics of residents in restraints and the type of restraint used.

Regulations for ICFs/MR currently include documenting requirements for **each use** of restraints and time out procedures that must be retained by the facility. HCFA will reevaluate these rules during its overall assessment of reporting requirements.

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As part of our overall effort to elevate awareness of the need to reduce the inappropriate use of restraints and seclusion in all care settings, HCFA is evaluating our expectations of State Medicaid agencies with regard to their role in promoting and protecting the rights of individuals who are served in residential treatment facilities.

HCBS waivers serve as the statutory alternative to institutional care. States are required to make annual reports to HCFA on the health and welfare of the individuals served through their waiver programs. HCFA is committed to understanding the extent of the problem of the use of seclusion and restraints affecting older persons and individuals with disabilities. We are seeking more information on the frequency of restraint use in these populations and are working with States and Regional Offices to develop specific guidance for monitoring HCBS waivers.

Recommendation #4: The report recommends that the HCFA Administrator require that any inpatient or residential facility that treats individuals with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds ensure that staff regularly receives training and refresher courses in alternate methods to handle agitated or potentially violent patients and document their receipt of training.

Response: HCFA agrees with this recommendation and has already established such a requirement for hospitals. The patient's rights section of the Condition of Participation (CoP) requires that, "All staff who have direct patient contact must have ongoing education and training in proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraint or seclusion."

HCFA recently implemented enhanced survey procedures and guidelines for the prevention of abuse and neglect in nursing homes. This improved guidance directed surveyors to assess the policies and procedures a nursing home has in place to prevent abuse or neglect. One aspect of a facility's process that will be reviewed is the training program for staff that addresses the appropriate treatment of residents. HCFA will reassess the nursing home requirements to determine if additional training is needed based on comments received in response to the new hospital regulation.

The regulation for ICFs/MR have extensive staff training requirements in a number of areas, including abuse detection and prevention, and restraints use. Guidelines specify that staff are taught effective ways to address inappropriate behaviors and use their knowledge to correctly and consistently implement individual behavior plans.

We are examining the requirements of State Medicaid agencies to ensure basic protections for patient health and safety in residential treatment facilities. As part of this review, we will address staff training on the appropriate ways to handle patients with agitated or violent behavior.

Section 1915(c) of the Social Security Act permits States to offer HCBS waiver services as an

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alternative to institutional care. Under this authority, States may design and implement services not otherwise available under Medicaid. Section 1915(c)(2)(A) of the Social Security Act requires States to put into place necessary safeguards, including adequate standards for provider participation to protect the health and welfare of waiver participants. The provider standards that the State institutes must be reasonably related to the demands of the service(s) to be furnished and the settings in which they are delivered. States have the flexibility to design and offer whatever services, except room and board, they believe are necessary to prevent the institutionalization of the target population, and to ensure the health and welfare of the individuals served. However, because States are free to define the services provided, there have been no Federal mandates regarding the minimum qualifications for individuals furnishing these services. We believe the States are in a good position to define the services they will utilize to implement their HCBS waiver programs. In partnership with States, we are examining safeguards that could be put in place for services furnished by the different types of providers of community-based services with a focus on the safety and well-being of our beneficiaries.

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