Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

RESTRAINTS AND SECLUSION

State Policies for Psychiatric Hospitals

JUNE GIBBS BROWN
Inspector General

AUGUST 2000
OEI-04-99-00150

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To describe State policies for restraints and seclusion in psychiatric hospitals.

BACKGROUND

Over five million people experience severe mental illnesses each year. In 1998, Medicare and Medicaid paid almost $6 billion to provide mental health care to over 500,000 beneficiaries in psychiatric hospitals. Mental health care may be provided in publicly (State) or privately owned hospitals. During hospitalization, persons with mental illness may be placed in restraints or seclusion.

The use of restraints and seclusion may be appropriate in some circumstances, but in others it may be inappropriate and abusive. In recent years, various reports have linked numerous deaths to inappropriate use of restraints and seclusion. Mental health advocates have expressed concern that hospitals are too quick to restrain or seclude patients, do not properly monitor them, and keep them restrained or secluded too long.

Such reports raised concern in the Congress, Department of Health and Human Services, and States on policies, standards and oversight for using restraints and seclusion. In response, the Health Care Financing Administration issued new Patients' Rights Condition of Participation regulations for hospitals, effective in August 1999. The new standards allow using restraints and seclusion in emergency situations, but only when less restrictive interventions are determined ineffective for ensuring the safety of patients and others.

FINDINGS

Many State policies already met some of the new Patients' Rights Condition of Participation standards. However, other State policies for both public and private psychiatric hospitals did not. State policies for use of restraints and seclusion in private psychiatric hospitals more frequently fell short of the new standards.

Initiating Restraints and Seclusion

The Health Care Financing Administration's new Patients' Rights Condition of Participation requires all staff with direct patient contact to have ongoing education and training in the appropriate and safe use of restraints and seclusion, and in alternative methods to avoid the use of restraints and seclusion.

State policies generally specify who can initiate a restraint or seclusion. In over 74 percent of the States only a doctor or nurse had authority to initiate a restraint or seclusion

in public psychiatric hospitals. Likewise, 73 percent of the States have the same restriction for private psychiatric hospitals. However, hospital staff said that in an emergency it is often necessary for the closest employee to restrain a patient until other trained staff arrive.

Physician Orders

The Health Care Financing Administration's new Patients' Rights Condition of Participation requires that a physician or other licensed independent practitioner "see and evaluate" the need for restraint and seclusion within 1 hour after the initiation of this intervention.

Policies for 78 percent of States require a physician order within 1 hour of initiating a restraint or seclusion in public psychiatric hospitals. Likewise, 60 percent did so for private psychiatric hospitals. However, most State policies did not specify a "see and evaluate" requirement. To illustrate, only 2 States required their public hospitals to meet the "see and evaluate" requirement. None did so for private hospitals. The other States allowed physician orders for restraint and seclusion to be given over the telephone.

In their response to the Health Care Financing Administration's new Patients' Rights Condition of Participation interim final rule, private associations for physicians and hospitals voiced opposition to the new 1 hour "see and evaluate" requirement. They said it will be costly and difficult to implement. They also believe the requirement inappropriately dictates medical practice.

Time Limits

The Health Care Financing Administration's new Patients' Rights Condition of Participation limits duration of physician and licensed independent practitioner orders for restraints and seclusion to 4 hours for adults. However, only 43 percent of States had a limit of 4 hours for public psychiatric hospitals. Only 9 percent of the States set such a limit for private psychiatric hospitals.

Further, only 20 percent of the State policies for physician orders in public psychiatric hospitals met the Health Care Financing Administration's new Patients' Rights Condition of Participation standard of a 2 hour time limit for adolescents, and a 1 hour limit for children. None of the States had similar standards for adolescents and children in private psychiatric hospitals.

Patient Monitoring

The Health Care Financing Administration's new Patients' Rights Condition of Participation requires continual (close, recurring) monitoring of patients that are either restrained or secluded. Many States met this standard. Eighty five percent of State policies for public psychiatric hospitals required monitoring every 15 minutes or less. Only 48 percent of the States required such monitoring in private psychiatric hospitals.

A few States had higher standards for patient monitoring. Four States required continuous (constant) monitoring in public psychiatric hospitals, while one State did so for private psychiatric hospitals.

RECOMMENDATION

We recommend that **HCFA work aggressively with States and accreditation organizations to quickly raise psychiatric hospital compliance with the new Patients' Rights Condition of Participation where necessary. Particular attention should be given to policies for private psychiatric hospitals.**

AGENCY COMMENTS

Both the Health Care Financing Administration and the Substance Abuse and Mental Health Services Administration commented on our draft report. Both concurred with our recommendation.

The Health Care Financing Administration has already initiated several activities that we believe will increase compliance with the new Patients' Rights Condition of Participation. For example, HCFA initiated efforts to educate key players such as State agencies, providers, accrediting organizations, and protection and advocacy groups on expected changes in treatment policies and procedures. Further, HCFA has initiated a training program for State and HCFA regional surveyors on the new Patients' Rights Condition of Participation.

The Substance Abuse and Mental Health Services Administration noted that our study is beneficial in that it provides baseline data on compliance with the new Patients' Rights Condition of Participation, and suggested several issues for further study. HCFA staff made similar comments to us in earlier discussion. We agree with the suggestion by SAMHSA and HCFA that more study is needed on the care and services provided to persons with mental illnesses. Our present study was one in a continuing series of studies, audits, and reviews on services to persons with mental illnesses. As we continue to analyze this subject in the future, we would expect to include coverage of some or all of the issues raised by SAMHSA and HCFA.

Both HCFA and SAMHSA also suggested several technical changes to the report for clarification. We made the changes where the scope of our study and facts obtained would support them.

We provide the full text of comments by both HCFA and SAMHSA in the Appendix.

INTRODUCTION

PURPOSE

To describe State policies for restraints and seclusion in psychiatric hospitals.

BACKGROUND

According to the 1999 Surgeon General's Report on Mental Health, over five million people experience severe mental illnesses each year. In 1998, Medicare and Medicaid paid almost $6 billion to provide mental health care to over 500,000 beneficiaries in psychiatric hospitals. That care is typically provided in two types of psychiatric hospitals: freestanding psychiatric hospitals and psychiatric units within acute care hospitals. Both types can be publicly owned or privately owned.

For the purpose of this report, public psychiatric hospital refers to State owned freestanding psychiatric hospitals and State owned psychiatric units within acute care hospitals. Private psychiatric hospital refers to privately owned freestanding psychiatric hospitals and privately owned psychiatric units within acute care hospitals.

Restraints and Seclusion

During hospitalization persons with mental illness may be placed in restraints or seclusion to prevent them from injuring themselves and others.

Restraint generally refers to methods for restricting a person's freedom of movement. Restraints can be chemical, physical, or mechanical. Chemical restraint refers to the use of drugs to control behavior or restrict a person's freedom of movement. In such instances, the drugs are not considered a part of standard medical or psychiatric treatment for the patient. Physical restraint generally involves restricting a person's movement by physical force. It is typically performed in an emergency to prevent a person from hurting themselves or others. Mechanical restraint generally refers to use of an external device, such as straps, belts, or cuffs to restrict a person's freedom of movement.

Seclusion is generally defined as involuntarily confining a person alone in a room from which the person is physically prevented from leaving.

Concern Over Use of Restraint and Seclusion

The use of restraints and seclusion may be appropriate in some circumstances, but in others it may be inappropriate and abusive. Generally, the Health Care Financing Administration's new Patients' Rights Condition of Participation regulations provide for the use of restraints and seclusion as an exception rather than normal practice for behavior management. To illustrate, it can be appropriate in emergency situations, but only when less restrictive interventions have been determined to be ineffective to ensure

safety of the patient and others. On the other hand, the regulations show that restraints and seclusion are inappropriate when imposed as a means of coercion, discipline, convenience, or retaliation by staff.

In recent years, reports of deaths and injuries resulting from inappropriate use of restraints and seclusion have raised serious concerns within the Congress, the Department of Health and Human Services, and States. For example, in September 1999, the General Accounting Office reported that 24 deaths associated with the use of restraints and seclusion occurred during fiscal year 1998. Previously, in October 1998, the Hartford Courant, a Connecticut newspaper, reported that 142 deaths resulted from inappropriate use of restraints in psychiatric facilities from 1988 through 1998 -- an 11 year period.

Oversight For Use of Restraints and Seclusion

A variety of State and Federal agencies and private sources provide oversight for patient care provided by psychiatric hospitals.

The Health Care Financing Administration (HCFA) has Federal oversight responsibility for the Medicare program. As such, HCFA establishes Federal requirements for psychiatric hospitals to participate in Medicare funded programs. The requirements are published as general and Special Conditions of Participation.

HCFA's new Patients' Rights Condition of Participation became effective as part of the Medicare general Condition of Participation in August 1999. They place two standards on all hospitals using restraints and seclusion. One standard provides guidance for the use of restraints during acute medical and surgical care. The other provides guidance for using restraints and seclusion in emergency situations where a patient is violent or aggressive, and a danger to himself or others.

State mental health agencies have front line oversight responsibility for psychiatric hospitals. Generally, State Departments of Mental Health[1] have oversight responsibility for public psychiatric hospitals. State Licensure and Certification agencies[2] generally have oversight responsibility for private psychiatric hospitals. The State agencies certify that both public and private psychiatric hospitals comply with HCFA's general Condition of Participation, and applicable State laws and policies. The certification and licensure process authorizes psychiatric hospitals to participate in Medicare funded programs.

By Federal statute, hospitals accredited by the Joint Commission on the Accreditation of Healthcare Organizations are deemed to have met Medicare's general Condition of Participation. Of the 611 psychiatric hospitals that participate in the Medicare program,

[1]We used a general, common title for various individual State agencies that have oversight responsibility for publicly owned and operated psychiatric hospitals. The title for any specific State agency may vary from the common title we used. Also, in some States the agency may have responsibility for both the publicly and privately owned psychiatric hospitals.

[2]We chose a general, common title to represent the various individual State agencies that have oversight responsibility for privately owned and operated psychiatric hospitals. The title for the agency in specific States could be different. Also, in some States the agency may have responsibility for both publicly and privately owned psychiatric hospitals.

almost 94 percent (572) were accredited by the Joint Commission in 1999. The Joint Commission surveys its accredited hospitals every 3 years, at a minimum, to ensure they continue to comply with established Joint Commission standards, including those for restraint and seclusion. We anticipate that the Joint Commission will revise its standards to take into consideration the new Patients' Rights Condition of Participation.

However, neither Joint Commission accreditation, nor State licensure and certification alone allow free standing psychiatric hospital participation in the Medicare program. Free standing psychiatric hospitals are also required to meet two Special Conditions of Participation -- hospital staffing and medical record documentation. HCFA contracts with psychiatric clinicians to periodically review hospitals for compliance with the two special conditions.

Hospitals are required to document the use of restraints and seclusion in the patient's medical record. When HCFA's contracted clinicians find instances of restraint and seclusion use, they may initiate further investigation. However, the HCFA contractor surveys are only done about every 3 to 4 years.

Likewise, the Substance Abuse and Mental Health Administration funds a network of State Protection and Advocacy (P&A) organizations that provide oversight for persons with mental illness who reside in psychiatric hospitals. State P&A organizations monitor and investigate incidents of inappropriate use of restraint and seclusion.

METHODOLOGY

This is one in a series of planned inspections on the use, control, and impact of the use of restraints and seclusion in psychiatric hospitals. In this report, we ascertained what policies States had established for using restraints and seclusion in public and private psychiatric hospitals. We also compared State policies to the Health Care Financing Administration's new Patients' Rights Condition of Participation regulations. Subsequent reports will focus on reporting systems for restraint and seclusion use, and for patient abuse and death in psychiatric hospitals.

Data Collection

Our findings are based largely on self-reported information provided by State Mental Health and Licensing agencies, and Protection and Advocacy organizations. Using a standardized written data collection instrument, we surveyed agencies in all 50 States and the District of Columbia that provide policy guidance and oversight for public and private psychiatric hospitals. Likewise, we surveyed Protection and Advocacy organizations in each of the 50 States and the District of Columbia.

We received responses from 43 State Mental Health Departments that provide oversight for State owned psychiatric hospitals -- a response rate of 84 percent. We received 36 responses from State Licensing and Certification agencies that provide oversight for privately owned psychiatric hospitals -- a response rate of 71 percent. In some States, one agency provided responses for both State and privately owned hospitals. Finally, 44

State Protection and Advocacy organizations responded to our survey -- a response rate of 86 percent. The Protection and Advocacy organizations responses encompassed both State and privately owned psychiatric hospitals.

We received survey responses from July through September 1999. This time period preceded and overlapped the issuance of the Health Care Financing Administration's final version of the new Patients' Rights Condition of Participation regulations.

Therefore, the new standards had not been fully implemented by States at the time of our inspection. However, where possible we compared existing State policies to the new Patients' Rights Condition of Participation regulations. As a result, our study provides an early snapshot of State policies at the time the new Patients' Rights Condition of Participation became effective. This snapshot provides a baseline for measuring progress in implementing the new requirements, and insight into policies that need special attention in the early stages of implementation.

We did not audit the self-reported information. However, we supplemented and corroborated it through interviews with officials and staff in a variety of Federal and State agencies, advocacy and trade organizations, and psychiatric hospitals. To illustrate, we interviewed officials and staff from the following organizations:

- The Health Care Financing Administration,
- Substance Abuse and Mental Health Services Administration,
- State Departments of Mental Health,
- State Licensing and Certification agencies,
- State Protection and Advocacy organizations,
- National Association of Protection and Advocacy Systems,
- National Association of State Mental Health Program Directors,
- National Alliance for the Mentally Ill, and
- Public and private psychiatric hospitals.

Additionally, we conducted document and literature searches. We analyzed State laws, regulations, and policies on the use of restraints and seclusion. We also reviewed professional trade journals and publications, and audit and evaluation reports on the use of restraints and seclusion in psychiatric hospitals.

Data Analysis

We integrated and synthesized data from various sources, identifying common characteristics and major differences. Additionally, we compared the policies in public and private psychiatric hospitals.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Initiating Restraints and Seclusion

HCFA's New Patients' Rights Condition of Participation

HCFA's new Patients' Rights Condition of Participation requires all hospital staff who have direct patient contact to have on-going education and training in the proper use of restraint and seclusion application and techniques. The regulation also requires education and training in alternative methods for avoiding the use of restraint and seclusion.

State Policies

State policies generally specify who can initiate a restraint or seclusion. Most State policies for both public and private psychiatric hospitals required a nurse or physician to initiate a restraint or seclusion. Over 74 percent of the States restricted authority to a nurse or doctor for initiating a restraint or seclusion in public psychiatric hospitals, and 73 percent have the same restriction for private hospitals.

Table 1
Initiating Restraints and Seclusion

Who Can Initiate	State Policies For Public Hospitals		State Policies For Private Hospitals	
Nurse or Physician	29	74.4%	19	73.1%
Hospital Policy	8	20.5%	7	26.9%
Unknown	2	5.1%	0	0.0%
Subtotal	39	100.0%	26	100.0%
No Answer	4	9.3%	10	27.8%
Total	43		36	

As Table 1 shows, 21 percent of the States allowed each public psychiatric hospital to establish who was authorized to restrain or seclude a patient. Likewise, 27 percent of the States allowed private psychiatric hospitals to set their own policy. In such States, the policies did not prescribe who was authorized to restrain or seclude a patient. These States allowed hospitals to use "any trained," "authorized," or "qualified staff." One State policy for private psychiatric hospitals allowed "anyone" to restrain or seclude a patient in an emergency situation.

The Protection and Advocacy staff we interviewed generally expressed concern about such policies. They expressed a belief that allowing someone other than a physician or nurse to initiate a restraint or seclusion increased the risk that it may be unnecessary or inappropriate. Mental health advocates told us that one of the most dangerous moments for restrained patients is during the "take-down." A take-down refers to when a patient is forced down and immobilized for application of a restraint. It is during this quick, often frantic, period that a patient can sustain serious injury and even death. The Hartford Courant reported that 23 of 142 restraint-related deaths occurred while patients were being restrained in face-down floor holds.

Hospital officials and staff we interviewed told us, however, that in an emergency, the patient and others could be in danger. Therefore, they said it is often necessary for the closest employee to restrain a patient until other trained staff arrive.

Physician Orders

HCFA's New Patients' Rights Condition of Participation

HCFA's new Patients' Rights Condition of Participation requires that a physician or other licensed independent practitioner "see and evaluate" the need for restraint and seclusion within 1 hour after the initiation of this intervention.

State Policies

As Table 2 shows, the policy in 27 percent of the States required that public psychiatric hospitals "immediately" obtain a physician order when a patient is restrained or secluded. Only 16 percent of the States had a similar requirement for private hospitals. Seventy eight percent of the States required public psychiatric hospitals to obtain physician orders within one hour of initiating a restraint or seclusion. For private psychiatric hospitals, 60 percent of States had the same one hour requirement.

However, only 2 State policies required their public hospitals to meet the "see and evaluate" requirement. None did so for private hospitals. The other States allowed physician orders for restraints and seclusion to be given over the telephone.

Also, 8 percent of the States allowed public hospitals in excess of one hour to obtain a physician order after a patient had been restrained or secluded. In contrast, 16 percent of the States allowed in excess of one hour for private psychiatric hospitals to obtain a physician order after a patient had been restrained or secluded. Of the States that allowed over one hour, one allowed public psychiatric hospitals, and two allowed private psychiatric hospitals, more than 24 hours to obtain the required physician order.

Table 2 Time Requirements For Obtaining Physician Orders				
Time Period Options	State Policies For Public Hospitals		State Policies For Private Hospitals	
Immediately	10	27.0%	4	16.0%
Within 15 minutes	2	5.4%	1	4.0%
16-30 minutes	4	10.8%	1	4.0%
31-60 minutes	13	35.1%	9	36.0%
1 to 8 hrs	2	5.4%	2	8.0%
Over 8 hrs	1	2.7%	2	8.0%
Hospital Policy	2	5.4%	5	20.0%
Not specified	3	8.1%	1	4.0%
Subtotal	37	100.0%	25	100.0%
No Answer	6	14.0%	11	30.6%
Total	43		36	

Views of Provider and Advocacy Groups

In their response to HCFA's new Patients' Rights Condition of Participation interim final rule, physician and hospital groups, such as the American Hospital Association, the National Association of Psychiatric Health Systems, and the American Psychiatric Association, expressed concern about the new one hour "see and evaluate" requirement. The groups expressed concern that requiring a face-to-face evaluation will increase costs and may be difficult for rural and private psychiatric hospitals to implement. The groups also believe that the requirement inappropriately dictates medical practice.

The mental health advocates from the State Protection and Advocacy system and National Alliance for the Mentally Ill stressed the importance of a face-to-face physician evaluation before, or at a minimum immediately after, placing a patient in restraint or seclusion. Requiring a physician to "see and evaluate" a patient before issuing an order, or immediately after restraint or seclusion, allows the physician to determine if the restraints or seclusion is warranted, or if another form of intervention is appropriate. Further, in situations where a physician determines that restraint or seclusion is appropriate, the physician can then determine that it is properly applied.

Another reason the advocates gave for requiring a physician to immediately evaluate a patient that has been restrained or secluded is that it allowed the physician to quickly provide needed medical treatment for any injuries sustained during the restraint procedure. The Hartford Courant series of articles emphasized the importance of early medical attention to any injuries incurred during a restraint process. For example, one article described a situation where an 11-year-old boy died as a result of a crushed chest sustained during the restraint process. Hospital staff who restrained the boy ignored his complaints of injury. The boy was dead before a physician ever examined him.

Time Limits

HCFA's New Patients' Rights Condition of Participation

HCFA's new Patients' Rights Condition of Participation limits the duration of each written restraint or seclusion order to 4 hours for adults, 2 hours for adolescents age 9 to 17, and 1 hour for children under age nine. Original orders may be renewed for up to a total of 24 hours before requiring a second face-to-face physician or licensed independent practitioner evaluation.

State Policies

The State policies in 43 percent of the States limited restraint and seclusion orders in public psychiatric hospitals to between 1 and 4 hours in duration. Conversely, only 9 percent of the States had a similar limit for restraint and seclusion orders in private psychiatric hospitals. Table 3 shows State policies for time limits on restraints and seclusion for both public and private psychiatric hospitals.

As Table 3 shows, 11 percent of the States did not establish physician order time limits for public psychiatric hospitals. Almost 35 percent of the States did not establish physician order time limits for private psychiatric hospitals. In such instances, the hospitals established their own policies.

Table 3
Requirements on the Duration of Restraint and Seclusion Orders

Time Limits	State Policies For Public Hospitals		State Policies For Private Hospitals	
1-4 hours	15	42.9%	2	8.7%
5-14 hours	4	11.4%	6	26.1%
24 hours	8	22.9%	5	21.7%
Hospital Policy	4	11.4%	8	34.8%
Unknown	4	11.4%	2	8.7%
Subtotal	35	100.0%	23	100.0%
No Answer	8	18.6%	13	36.1%
Total	43		36	

Seven of the 15 States told us their State policy varied between 1and 4 hours in duration for physician orders in public psychiatric hospitals. The time limits varied depending on a patient's age. All seven State policies were identical to the new Condition of Participation: 4 hours for adults, 2 hours for adolescents 9 to 17 years of age, and 1 hour for children under 9 years of age. None of the State policies for private hospitals made this distinction.

The mental health professionals we interviewed agreed that restraint and seclusion physician orders should be time limited. They said patients should be frequently evaluated and released as soon as possible. The importance of this guidance was emphasized by the Hartford Courant article that related a death to a lengthy restraint. In that instance, a 38 year-old man died from medical complications after being restrained to a bed for 18 hours. Such adverse outcomes highlight the importance of frequently evaluating patients who are restrained or secluded. A short time limit on restraint and seclusion physician orders requires frequent oversight and evaluation of patients.

Patient Monitoring

HCFA's New Patients' Rights Condition of Participation

HCFA's new Patients' Rights Condition of Participation requires continual (close, recurring) assessment, monitoring, and reevaluation of patients that are either restrained or secluded. However, for persons that are both restrained and secluded the Condition of Participation requires continuous (constant) monitoring face-to-face by an assigned staff or by staff using both audio and video equipment.

State Policies

As Table 4 shows, eighty five percent of public psychiatric hospitals, and 48 percent of private psychiatric hospitals meet the continual (close, recurring) standard of the new Patients' Rights Condition of Participation by requiring patient monitoring every 15 minutes or less. Four States had a higher standard of monitoring than the new Patients' Rights Condition of Participation by requiring continuous (constant) monitoring for patients in public psychiatric hospitals. One State did so for private psychiatric hospitals.

One State allowed patient monitoring in both public and private psychiatric hospitals on two hour intervals. In addition, one State had no specific policy on frequency of monitoring for restrained and secluded patients in private psychiatric hospitals.

Table 4 Requirements for Frequency of Monitoring				
Time Periods	State Policies For Public Hospitals		State Policies For Private Hospital	
Continuous	4	10.0%	1	3.7%
15 minutes	30	75.0%	12	44.4%
30 minutes	0	0.0%	2	7.4%
1 hour	2	5.0%	2	7.4%
2 hours	1	2.5%	1	3.7%
Unknown	2	5.0%	2	7.4%
Hospital Policy	1	2.5%	6	22.2%
No Policy	0	0.0%	1	3.7%
Subtotal	40	100.0%	27	100.0%
No Answer	3	7.0%	9	25.0%
Total	**43**		**36**	

The type and frequency of monitoring is important for the safety of persons in restraints or seclusion. To illustrate, improperly applied restraints that are harmful to patients may go undetected unless patients are adequately monitored. One such example was related to us by a State Protection and Advocacy organization. They described an incident where a nurses' aide restrained a 45 year-old woman to her bed at about 8:30 p.m. without a physician's order. The aide had not been trained in applying restraints. The woman was left restrained and unchecked overnight. Almost 10 hours later, she was found dead on the floor with the restraints bunched around her neck and chest.

RECOMMENDATION

Many State policies already met some of the new Patients' Rights Condition of Participation standards. However, other State policies for both public and private psychiatric hospitals did not. State policies for use of restraints and seclusion in private psychiatric hospitals more frequently fell short of the new standards.

Therefore, we recommend that **HCFA work aggressively with States and accreditation organizations to quickly raise psychiatric hospital compliance with the new Patients' Rights Condition of Participation where necessary. Particular attention should be given to policies for private psychiatric hospitals.**

AGENCY COMMENTS

Both the Health Care Financing Administration and the Substance Abuse and Mental Health Services Administration commented on our draft report. Both concurred with our recommendation.

The Health Care Financing Administration has already initiated several activities that we believe will increase compliance with the new Patients' Rights Condition of Participation. For example, HCFA initiated efforts to educate key players such as State agencies, providers, accrediting organizations, and protection and advocacy groups on expected changes in treatment policies and procedures. Further, HCFA has initiated a training program for State and HCFA regional surveyors on the new Patients' Rights Condition of Participation.

The Substance Abuse and Mental Health Services Administration noted that our study is beneficial in that it provides baseline data on compliance with the new Patients' Rights Condition of Participation, and suggested several issues for further study. HCFA staff made similar comments to us in earlier discussion. We agree with the suggestion by SAMHSA and HCFA that more study is needed on the care and services provided to persons with mental illnesses. Our present study was one in a continuing series of studies, audits, and reviews on services to persons with mental illnesses. As we continue to analyze this subject in the future, we would expect to include coverage of some or all of the issues raised by SAMHSA and HCFA.
Both HCFA and SAMHSA also suggested several technical changes to the report for clarification. We made the changes where the scope of our study and facts obtained would support them.

We provide the full text of comments by both HCFA and SAMHSA in the Appendix.

Agency Comments

Health Care Financing Administration (HCFA)
Substance Abuse and Mental Health Services Administration (SAMHSA)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: AUG 10 2000

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Restraints and Seclusion: State Policies for Psychiatric Hospitals" (OEI-04-99-00150)

Thank you for the opportunity to review the above-mentioned report. This report underscores the compelling need for the Health Care Financing Administration's (HCFA's) new protections for hospital patients against the inappropriate use of seclusion and restraints. Last year, at the same time that the Inspector General was conducting this research, we established tough new requirements for hospitals to protect residents from the inappropriate use of restraints and seclusion. The research looked largely at state inspection activities prior to when these stronger protections and requirements took effect in August 1999. HCFA published its new Patients' Rights Condition of Participation Rule in July 1999, which became effective in August 1999. This study examined data from July 1999 to September 1999.

The Patients' Rights Conditions of Participation Rule covered restraint and seclusion standards for both behavior management and acute medical and surgical care. Since the implementation of the interim final rule, efforts have been made to inform State Agencies (SAs), providers, accrediting organizations, and protection and advocacy groups about the expected changes in the treatment policies and procedures that should be incorporated into services delivered by the provider. These changes underscore our determination to ensure the basic protections for all patients and reaffirms our commitment to patient rights.

Although the study was conducted before the rule had been fully implemented, the report affirms the importance of our Patients' Rights Conditions of Participation Rule. We remain committed to protecting the health and safety of patients in psychiatric hospitals, and specifically, to ensuring that patients are not subjected to the inappropriate use of restraints and seclusion. In fact, since the OIG undertook this research, we have conducted special training for state inspectors to ensure that they understand and properly enforce the new patients' rights conditions of participation. We urge the OIG to conduct additional research to determine how well states are enforcing these requirements today.

Our specific comments to the report's recommendation are attached. We have also attached some technical comments.

Attachment

OIG RECOMMENDATION:

HCFA should work aggressively with States and accreditation organizations to quickly raise psychiatric hospital compliance with the new Patients' Rights Condition of Participation where necessary. Particular attention should be given to policies for private psychiatric hospitals.

We concur with the recommendation and offer the following clarifications:

The Patients' Rights Condition of Participation (CoP) regulates the use of restraints and seclusion for both general, acute care hospitals and psychiatric hospitals. The rule sets forth the right for patients to be free from restraint or seclusion. The regulation allows restraints and/or seclusion only if they are to protect the patient and/or staff or others from harm in an emergency situation, and only as a last resort. The CoP supports:

- Individualized, thorough patient assessment;
- The use of the least restrictive intervention possible;
- Continual reassessment and monitoring of the restrained patient to protect his or her safety;
- Staff training to educate staff in correct restraint application, skills for assessing patient status, and alternative interventions; and
- The reporting of patient deaths related to restraints or seclusion use.

These provisions are enforced by State survey agencies in response to complaints. Failure to meet the requirements of this CoP can result in the termination of the hospital's provider agreement. The report also states that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) surveys its accredited hospitals every 3 years, at a minimum, to ensure they continue to comply with established Joint Commission standards, including those for restraints and seclusion. HCFA has recently become aware that only psychiatric units that elected to be surveyed using the JCAHO's Behavioral Health Manual historically have been reviewed for restraints and seclusion. We are looking into this issue and will determine who is, or should be, surveying for restraints and seclusion in hospital psychiatric units.

We also want to note that training was provided in June 2000 to SAs and Regional Office (RO) surveyors on the new Patients' Rights Condition of Participation. This training is now a regular component of our annual training. We have developed guidelines and survey procedures to more rigorously apply these requirements. HCFA has also increased the number of Federal oversight surveys and has requested additional funds, for a total of two million dollars, to further increase the number of surveys for psychiatric hospitals over the next two fiscal years.

Finally, HCFA continues to search for ways to keep SAs and accreditation organization current with our expectations. We are exploring the use of a web site, conference calls, and satellite broadcasts to better reach SAs and accreditation organizations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services
Center for Substance Abuse Prevention
Center for Substance Abuse Treatment
Rockville MD 20857

AUG 3 2000

TO: June Gibbs Brown
Inspector General

FROM: Administrator

SUBJECT: Comments on OIG Draft Report: *Restraints and Seclusion: State Policies for Psychiatric Hospitals* (OEI-04-99-00150)

Thank you for the opportunity to review the subject report. In general, the Substance Abuse and Mental Health Services Administration (SAMHSA) thinks the report will be beneficial in providing baseline data on State compliance with the recent Health Care Financing Administration (HCFA) Patients' Rights Condition of Participation. We would like to offer the following comments:

General Comments:

- We suggest that a similar review of State compliance with Patients' Rights Condition of Participation be conducted in 1 to 2 years to assess State progress in this area. Additionally, we suggest that a similar study examine State compliance with the forthcoming release of HCFA standards on restraints and seclusion for facilities serving those under age 21.
- While the report identifies that private psychiatric hospitals' restraint and seclusion policies do not meet HCFA standards, it does not indicate the number of these facilities that are not receiving Medicare payments and therefore are not subject to these standards. This points to the potential gap in relying solely on HCFA regulations to reduce the misuse of restraint and seclusion.
- The scope of the report does not cover other facilities, for example residential congregate living facilities, that do not receive Medicare payments but have had reports of restraint and seclusion misuse. We would like to suggest the need for a study on the policies of these facilities.

Office of the Administrator—Office of Applied Studies—Office of Communications—Office of Equal Employment Opportunity & Civil Rights—Office of Managed Care—Office of Minority Health—Office of Policy & Program Coordination—Office of Program Services

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Specific Comments:

- On Page 4, first paragraph, in the Background section, it should refer to the Surgeon General's Report on Mental "Health"–rather than "Illness."

- On Page 4, first paragraph, in the Background section, second sentence under the heading Concern Over Use of Restraint and Seclusion, it refers to HCFA's Patients' Rights Condition of Participation regulations permitting restraint and seclusion use as an exception for "behavioral management." We suggest that this sentence be revised since behavioral management refers to controlling patient behavior and restraint refers to managing emergency situations.

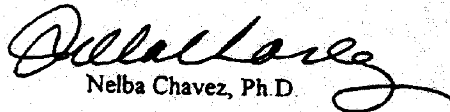
- On Page 5, in the Background section, under the heading Oversight for Use of Restraints and Seclusion, we suggest that this part be revised to include a description of the role that the State Protection and Advocacy organizations play in providing oversight for patient care, particularly since they were one of the groups surveyed.

- On Page 6, first paragraph, last sentence, states that "...the Joint Commission (on Accreditation of Healthcare Organizations (JCAHO)) will revise its standards to take into consideration the new Patients' Rights Condition of Participation." The JCAHO has, in fact, revised its restraint standards. There are, however, discrepancies between JCAHO and HCFA regulations, notably on the "one-hour" assessment rule. This identifies another recommendation for HCFA to assure that accreditation agencies are actively monitoring full compliance with all standards.

- On Page 9, in the Findings section, under the heading Physician Orders, we suggest that the description of HCFA's standards identify the requirements for physician orders and "one-hour" assessments.

- On Page 14, in the Recommendation section, we encourage particular attention to raising State compliance with meeting the Patients' Rights Condition of Participation for children given the findings on time limits and the high vulnerability for death and injury in this population.

If you have any questions or need further information, please contact Delores Q. Christie, SAMHSA OIG Liaison on (301) 443-4543.



Nelba Chavez, Ph.D.