



## Implementation Guidelines: 14 NYCRR §526.4 Restraint and Seclusion

**Note:** These guidelines are based in part on CMS manual system pub 100-07 state operations provider certification Appendix A – survey protocol, regulations and interpretive guidelines for hospitals, issued by the Department of Health and Human Services.

### 14 NYCRR §526.1 Background and Intent:

***Facility policies and procedures should support the general intent behind the restraint and seclusion regulations.***

The intent of this standard is to convey the critical need to ensure that care provided to persons with mental illness in the State of New York is offered in a safe and therapeutic environment. Also implicit in this standard is the expectation that facilities operated or licensed by OMH will be actively engaged in efforts to reduce the use of restraint and seclusion in facilities operated, certified, or monitored by OMH. The stated goal of these efforts is to reduce restraint and seclusion to the status of rare events, to reduce the behavioral emergencies that have prompted their use, and, wherever possible, to entirely eliminate the use of restraint.

The use of restraint and seclusion is associated with increased risk of injury to both patients and staff who utilize these interventions. Seclusion and restraint also may have deleterious effects on patients, including survivors of sexual trauma and/or physical abuse, and patients with hearing impairments who are unable to communicate without the use of their hands. Physical risks include serious injury or even death, and psychological injuries include retraumatization for individuals with histories of abuse.

It is the experience of the Office of Mental Health (OMH) that the use of seclusion and restraint for purposes of managing violent or self-destructive behavior can be significantly reduced through the creation and maintenance of environments which promote hope, recovery and the empowerment of patients, identify and implement strategies to advance positive behavior management and restraint reduction efforts, incorporate strategies in hiring or workforce development practices to advance these efforts, and emphasize the education and sensitization of staff regarding the risk and safe use of restraint and seclusion. It is therefore OMH's expectation that all facilities authorized to utilize restraint and seclusion will develop, and actively implement, policies and procedures that encourage these results.

Facility leadership is responsible for creating a culture that supports a reduction in the use of restraint and seclusion. Leadership must ensure that systems and processes are developed, implemented, and evaluated that support positive therapeutic environments, the use of effective crisis prevention and de-escalation strategies and an elimination of the inappropriate use of restraint and seclusion. To this end, leadership should:

- assess and monitor the use of restraint and seclusion in their facility;

- implement actions to ensure that restraint and seclusion is used only as a measure of last resort to avoid imminent injury to the patient, staff, or others; and ensure that the facility complies with the requirements set forth in 14 NYCRR Section 526.4, as well as applicable federal requirements and facility policy, whenever restraint or seclusion must be used.

**§526.3 Applicability** [also see §526.4(c)(14) Special program requirements]:

***Compliance with these regulations is required of State operated psychiatric centers, hospitals and inpatient facilities, CPEPS, and RTFs.***

The following types of providers are authorized to utilize restraint and seclusion, and thus are subject to the provisions of 14 NYCRR Part 526 governing its use:

1. State Operated Psychiatric Centers;
2. Hospitals and Inpatient Facilities governed by 14 NYCRR Parts 580 and 582;
3. Residential Treatment Facilities for Children and Youth governed by 14 NYCRR Part 584; (please note that the use of seclusion in RTFs must be authorized by OMH in accordance with an approved plan); and
4. Comprehensive Psychiatric Emergency Programs governed by 14 NYCRR Part 590, if there is an approved written plan.

The regulations specify that restraint and seclusion is NOT authorized in any other program category, unless the regulations that establish the program category expressly indicate that restraint and seclusion can be used. Therefore, the use of restraint and seclusion is not authorized in, and shall not be utilized in, outpatient treatment programs governed by 14 NYCRR Part 587 or Part 599 (clinic treatment programs (for adults or children/youth); continuing day treatment programs; day treatment programs serving children; partial hospitalization programs; or intensive psychiatric rehabilitation treatment programs); 14 NYCRR Part 595 (residential programs for adults); 14 NYCRR Part 594 (licensed housing programs for children); or 14 NYCRR Part 512 (personalized recovery oriented programs).

In situations in which alternative procedures and methods not involving the use of physical force cannot reasonably be employed, the regulations do not prevent a program of any category from using reasonable physical force when necessary to protect the life and limb of any person, for the purpose of restoring safety.

#### **§526.4(a) Definitions**

***Facility policies and procedures should employ definitions that are consistent with 14 NYCRR Section 526.4.***

- (3) “Drug used as a restraint” means a drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patients’ freedom of movement and is not a standard treatment or dosage for a patient’s medical or psychiatric condition, or**

**as otherwise defined in federal regulations of the Centers for Medicare and Medicaid Services.**

Drugs or medications that are used as part of a patient's standard medical or psychiatric treatment, and are administered within the statutory dosage for the patient's condition, would not be considered "drug used as a restraint." These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, antianxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management.

The Office of Mental Health does not consider the use of medication as a restraint to be a standard practice. However, there may be emergency situations where the degree of harm posed by a patient's behavior is such that the primary intent of a physician in ordering a medication is to restrict the ability of the patient to engage in the dangerous behavior, thereby minimizing harm to the patient and others. When medication is used in this manner, there must be a STAT (immediate one-time) order for the medication, and the use of the medication must also be identified as a restraint.

Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications, is a standard treatment or dosage for the patient's condition includes all of the following:

- The drug or medication is used within the pharmaceutical parameters approved by the federal Food and Drug Administration and the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters;
- The use of the drug or medication follows national practice standards established or recognized by the medical community, or professional medical associations or organizations;
- The use of the drug or medication to treat a specific patient's clinical condition is based on that patient's symptoms and overall clinical situation, and on the physician's or other licensed independent practitioner's knowledge of that patient's expected and actual response to the medication.

Another component of "standard treatment or dosage" for a drug or medication is the expectation that the standard use of a drug or medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him/her than would be possible without the use of the drug or medication. If the overall effect of a drug or medication, or combination of drug or medications, is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the drug or medication is not being used as a standard treatment or dosage for the patient's condition.

Whether or not an order for a drug or medication is STAT (immediate one-time order), PRN (as needed) or a standing order does not determine whether or not the use of that drug or medication is considered a restraint. The determining factor in whether or not medication is used as a restraint is the purpose for which the medication is being ordered. If the patient's behavior has risen to a

level where there is an imminent risk of serious injury to the patient or others, and the purpose of the medication is to “disable” the patient, the medication is a restraint. If the primary purpose of a drug is to calm a patient to “enable” him or her to remain in the therapeutic milieu, the medication is not being used as a restraint. *The use of PRN or standing order drugs or medications is prohibited if a drug or medication meets the definition of a drug or medication used as a restraint.*

As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint. For example, a patient may be agitated due to pain or adverse reaction to an existing drug or medication or other unmet need or concern.

When a drug is used as a restraint, monitoring and observation must include post-medication administration assessment by qualified professional staff. The same monitoring requirements as mechanical or manual restraint apply, provided, however, that monitoring of vital signs should be done more frequently than with mechanical or manual restraint, in accordance with good clinical practice.

It is important to note that the use of a drug or medication as a restraint does not supersede a patient’s right to object to medication as otherwise set forth in Section 527.8 of Title 14 NYCRR.

- (6) “Manual restraint” means the use of a manual or physical method to restrict a person’s freedom of movement or normal access to his or her body. The term “manual restraint” means and includes the term “physical restraint.”**

Based upon this definition, manual restraints include, but are not limited to, physical restraints required to facilitate the safe administration of court ordered or emergency medications administered over the patient’s objection and other physical interventions that are designed to involuntarily hold or pin the patient to restrict movement. Furthermore, a physical “takedown” to the floor is always considered a manual restraint.

The physical holding of a patient for the purpose of conducting routine physical examinations or tests, probably does not meet the definition of “manual restraint.” However, patients do have the right to refuse treatment (see 14 NYCRR Parts 27.8 and 527.8). Holding the patient in a manner that restricts a patient’s movement against a procedure or test to which he or she has the right to object, in accordance with such Parts, is considered a manual restraint. Also included in the definition of manual restraint are holds that are commonly referred to as “therapeutic holds.” Nationally, many deaths have occurred while employing these practices. Physically holding a patient can be just as restrictive, and just as dangerous, as restraining methods that involve devices.

For the purposes of these regulations, a staff member picking up, redirecting, or holding a child to comfort him/her is not considered restraint. Also not included in the definition of a restraint is a physical escort, which is a light grasp to escort a patient to a desired location.

If the patient can easily remove or escape the grasp, this would not be considered manual restraint. However, if the patient cannot easily remove or escape the grasp, this would be considered manual restraint and all of the procedural requirements for restraint would apply.

- (7) **“Mechanical restraint” means an apparatus which restricts a patient’s movement of the head, limbs, or body, and which the patient is unable to remove, provided, however, this term may also apply to an apparatus not normally used for this purpose, such as a bed rail or bed sheet, if the patient is not able to release the mechanism.**

Because the definition of mechanical restraint does not name each device and situation that can be used to immobilize or reduce the ability of a patient to move his or her arms, legs, body or head freely, it promotes looking at each patient situation on a case by case basis. Generally, if a patient can easily remove a device, the device would not be considered a restraint. In this context, “easily remove” means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as was applied by the staff (e.g., side rails are put down, not climbed over, buckles are intentionally unbuckled, ties or knots are intentionally untied, etc.), considering the patient’s physical condition and ability to accomplish the objective. A determination as to whether something is “easily removed” is based on a patient’s physical and cognitive abilities to remove a restriction within a brief time span.

Restraint alternatives, such as chair or bed “sentinels,” which patients themselves may release, may be useful in the care of certain patients, such as those who are elderly or confused, who may otherwise injure themselves.

A restraint does not include methods that protect a patient from falling out of bed. Examples include raising side rails when a patient is on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. The use of side rails in these situations prevents the patient from falling out of the bed and therefore would not be considered a restraint based on this definition.

However, side rails are frequently not used as a method to prevent a patient from falling out of bed, but instead, used to restrict the patient’s freedom to exit the bed. The use of side rails to prevent the patient from exiting the bed would be considered a restraint and would be subject to all the procedural requirements of these regulations applicable to restraints. If all 4 side rails are raised in order to restrain a patient (as defined in these regulations), then the requirements set forth in these regulations apply. Raising fewer than 4 side rails when the bed has segmented side rails would not necessarily immobilize or reduce the ability of a patient to move freely, as defined in these regulations. For example, if the side rails are segmented and one segment is not raised to allow the patient to freely exit the bed, the side rails are not acting as a restraint. In addition, if a patient is not physically able to get out of bed, regardless of whether or not the side rails are raised, raising all 4 side rails would not be considered restraint because the side rails have no impact on the patient’s freedom of movement.

Placement in a crib with raised rails is an age-appropriate standard safety practice for infants or toddlers. Placement of an infant or toddler in a crib with raised rails would not be considered restraint. For a child who is not an infant or toddler, placement in a crib with raised rails may well be considered restraint.

- (8) **“Mechanical support” means a device intended to keep the person in a safe or comfortable position or to provide the stability necessary for therapeutic measures such as immobilization of fractures, administration of intravenous solutions or other medically necessary procedures, which the patient can remove at will.**

A mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint under these regulations.

The use of mitts and helmets as an emergency intervention to avoid imminent injury to the patient or others constitutes a restraint under these regulations, as are, by extension, each of the following: pinning or otherwise attaching mitts to bedding, or using a wrist restraint in conjunction with hand mitts; applying the mitts so tightly that the patient's hand or fingers are immobilized; or using mitts that are so bulky that a patient's ability to use his/her hands is significantly reduced.

- (12) “Restraint” means any manual method, mechanical device, or pharmacologic measure which immobilizes or reduces the ability of an individual to freely move his or her arms, legs, body, or head. This includes manual restraint, drug used as a restraint, and mechanical restraint,**

Under this definition, commonly used practices and devices could meet the definition of restraint, such as:

- tucking a patient's sheets in so tightly that the patient cannot move;
- use of a “net bed” or an “enclosed bed” that prevents the patient from freely exiting the bed;
- using side rails to prevent a patient from voluntarily getting out of bed.

Handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices are considered law enforcement safety devices and are not acceptable health care restraint interventions for use by facility staff to restrain patients. Such devices are permitted when employed by safety or law enforcement staff for the transport of patients under Article 10 of the Mental Hygiene Law, or patients committed to the custody of the Commissioner pursuant to a criminal court order, or if otherwise permitted in law.

The use of weapons, (such as pepper spray, mace, nightsticks, tasers, cattle prods, stun guns, and pistols), is not a safe, acceptable health care intervention for use by facility staff to restrain patients. The use of weapons by any facility staff in subduing a patient in order to place the patient in restraint or seclusion should never be permitted.

- (13) “Seclusion” means the involuntary confinement of a patient in a room or area where the patient is prevented from leaving, (or where the patient reasonably believes that he or she will be prevented from leaving), with no ability to meaningfully interact with other patients or staff, provided, however, it shall not mean confinement on a locked unit or ward where a patient is with others.**

Seclusion may only be used for the prevention of violent behavior or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Seclusion is not just confining a patient to an area, but involuntarily confining the patient alone in a room or area where the patient is physically, or cognitively, prevented from leaving.

If a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room, or if the actions of the staff can reasonably be interpreted as threatening the patient with physical intervention, or other implicit or explicit consequences, if the patient attempts to leave the room, the room is considered locked, whether or not the door is actually closed or locked. In this situation, the patient is being secluded. Conversely, if a staff member is in a room with a patient and is engaging in positive therapeutic interventions in an attempt to help the patient maintain or regain control, this would not be considered seclusion.

Confinement on a locked ward or unit where the patient is with others does not constitute seclusion. Also not considered seclusion is time out, which, based on the definition in these regulations, is an intervention in which the patient, either upon the recommendation of staff or at the patient's initiative, consents to spend time alone in a designated area from which the patient is not physically prevented from leaving. Therefore, the patient can leave the designated area when the patient chooses.

### **Best Practice Guidance - Sensory Modulation and Comfort Rooms**

Facilities are strongly encouraged to consider alternatives to seclusion, such as the use of sensory modulation and comfort rooms. A comfort room is a designated space that is designed in a way that is calming to the senses and where the user can experience visual, auditory, olfactory, and tactile stimuli. Furnished with items that are physically comfortable and pleasing to the senses, comfort rooms offer a sanctuary from stress and are a useful tool to teach individuals calming techniques in order to decrease agitation and aggressive behavior. In this regard, comfort rooms (which may also be utilized by staff, as appropriate) have great utility in fostering a safe and therapeutic environment. More information about comfort rooms can be obtained from OMH's public website: [www.omh.ny.gov](http://www.omh.ny.gov).

### **§526.4(b) General Principles**

#### ***Facility policies and procedures should reflect the following general principles:***

Restraint and seclusion can be used for purposes of managing violent or self-destructive behavior only as safety interventions in emergency situations when necessary to avoid imminent, serious injury to the patient or others, and less restrictive interventions (including any such interventions that have been identified in a patient's behavioral management plan) have been utilized and determined to be ineffective, or in rare instances where the patient's dangerousness is of such immediacy that less restrictive interventions cannot be safely employed.

The decision to use a restraint or seclusion is not driven by diagnosis, but by a comprehensive individual patient assessment conducted by a physician prior to implementation of the restraint or seclusion, or within an hour after implementation of the order. For a given patient at a particular point in time, this comprehensive individualized assessment is used to determine whether the use of less restrictive measures poses a greater risk than the risk of using restraint or seclusion. The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects may cause confusion, agitation, and combative behaviors. Addressing these medical issues may eliminate or minimize the need for the use of restraints or seclusion.

Safe patient care hinges on looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to the individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors. It is the expectation of the Office of Mental Health that facilities will direct their staff to immediately interact or intervene to prevent a patient from seriously injuring him/herself or others.

The use of restraint is inherently risky. Any restraint intervention employed in a given circumstance must be the least restrictive intervention that meets the patient's clinical needs and protects the safety of the patient, staff, or others. Ongoing documented assessments should demonstrate that the restraint or seclusion is the only reasonable alternative at the time (or at a time in the past) after all less restrictive interventions have been employed or are not feasible.

### **Best Practice Guidance- The impact of Restraint on Staff**

Any review of the use of restraint in a facility must include a review of its impact on staff. In accordance with the principles of trauma informed care, whenever the use of restraint is employed, it should be done in as kind and respectful a manner as possible to prevent retraumatization. Staff need to be in control of their emotions and physical actions at all times. Staff who see another staff member losing emotional or physical control should immediately take steps to either have that staff member leave and be replaced by another staff member, or to direct that staff member to immediately regain his or her own composure. The use of a comfort room by staff may be helpful in these circumstances.

### **§526.4(c) Restraint and Seclusion to Manage Violent or Self-Destructive Behavior**

#### ***Facility policies and procedures should reflect the following general principles:***

Restraint and seclusion for purposes of managing violent or self-destructive behavior must be implemented safely and appropriately and in accordance with New York State Law, including Mental Hygiene Law Section 33.04. It should only be utilized when less restrictive measures, including any such interventions that have been identified in a patient's behavior management plan, have been utilized and found to be ineffective to protect the patient from seriously injuring self or others; or in rare instances where the patient's dangerousness is of such immediacy that less restrictive interventions cannot be safely employed.

Utilization of seclusion or restraint to manage violent or self-destructive behavior shall not be based on a patient's seclusion or restraint history or on a history of dangerous behavior. The decision to use a restraint or seclusion is not driven by diagnosis, but by a determination by a physician following a comprehensive face-to-face assessment that, for a given patient at a particular point in time, the use of restraint or seclusion is the least restrictive intervention that will protect the physical safety of the patient, staff, or others.

It is important that facility policies governing the use of restraint or seclusion include provisions for appropriate attention to the personal needs of the patient, including toileting facilities, and medical and hygiene needs, by staff escort or otherwise, and for the patient's physical and mental comfort.



The physical environment shall be as conducive as possible to facilitating early release from restraint or seclusion, with attention to calming the patient with sensory interventions when clinically appropriate. Any space utilized for restraint or seclusion should include a clock within visual observation of the patient. Every effort must be made to protect the patient's privacy. A patient should never be placed in four-point or five-point restraints in public view, nor should more than one patient be restrained in a room.

With respect to mechanical restraint, only devices which have been authorized by the Commissioner for use in the management of violent or self-destructive behavior may be utilized for this purpose. No device can be utilized for this purpose unless it has been confirmed that the device at issue is on the Commissioner's approved list, which includes:

- four-point restraint
- five-point restraint
- wrist-to-belt restraint
- mitts
- helmets
- calming blanket

In addition, certain restraint techniques have been deemed by the Office to be dangerous and, in accordance with its authority in Mental Hygiene Law Section 31.19, cannot be utilized:

- any technique that obstructs a patient's respiratory airway or impairs his or her breathing or respiratory capacity, including techniques in which a staff member places pressure on a patient's back or places his or her body weight against the patient's torso or back;
- a technique that utilizes a pillow, blanket, or other item to cover the patient's face or to hold over or above the patient's face;
- use of any technique on a patient who has a known medical or physical condition where there is reason to believe that use of such technique would endanger the person's life or significantly exacerbate the person's medical condition; or
- restraint in a prone position.

If, at any time in the course of a restraint, a patient ends up in a prone position, he or she should be rotated to a face-up position immediately. In addition, if or when a restrained patient states that he or she cannot breathe, staff must immediately assess the patient and change the patient's position to facilitate breathing.

#### **(4) Patient Behavior Management History Assessment and Individual Crisis Prevention Plans:**

The initial assessment of a patient and development of an individual crisis prevention plan are primary prevention tools that are critical components of an overall strategy to reduce the use of restraint or seclusion. Facility policies must include provisions that address conducting an initial patient behavior management history assessment of each patient upon admission to the facility, or as soon thereafter as possible. Assessments of a patient's current condition, history, and risks are the foundation of any treatment plan, formal or informal, which is the basis for any care the patient receives in the hospital.

A document that identifies a patient's individual preferences and behaviors related to behavioral management interventions is often called an "individual crisis prevention plan," an "individualized

calming plan,” a “safety plan,” or similar reference. Regardless of what it is called, the development of such a document can be extremely useful in managing crisis situations and in reducing the use of restraint and seclusion. It is the expectation of the Office of Mental Health that facilities authorized to utilize restraint or seclusion will encourage the development of these plans, and document them in the clinical record.

### **Best Practice Guidance - Patient Behavior Management Assessment**

This assessment should include input from the patient and, when reasonably possible, anyone else he or she desires to be present, such as a family member, significant other, or authorized representative. Depending on the circumstances, the information gathered in the initial interview may be minimal. However, as clinicians gather more information and experience with the patient, the assessment will become more robust. A reassessment should be completed whenever there is a significant change in the patient’s physical or psychological condition. This assessment (and any subsequent reassessments) should include:

review of any advance directive or crisis plan the patient may present; the development or updating of an individual crisis prevention plan, personal safety plan, or similar document, which shall be used by the facility in treatment planning and de-escalation, and which allows a patient to identify:

early warning signs, triggers and precipitants of distress, stress or aggression, which cause the patient to escalate; techniques, methods or tools that help the patient to control his or her own behavior; and preferences, if any, relating to the gender of staff assigned to monitor a patient in restraint; identification of pre-existing medical conditions or any physical disabilities or limitations that would place the patient at greater risk during restraint and seclusion, e.g., obesity, cardiac conditions, pregnancy, asthma or other respiratory conditions, impaired gag reflex, back conditions, seizure disorders, deafness, blindness, or hemophilia; and

any trauma history, including any history of sexual or physical abuse the patient feels is relevant.

### **Best Practice Guidance - Individual Crisis Prevention Plan -**

An Individual Crisis Prevention Plan is more than just a plan. Fundamentally it is an individualized plan developed in advance to prevent a crisis and avoid the use of restraint or seclusion. It is a collaborative effort on the part of both the patient and staff to identify an agreed-upon strategy designed to assist the patient in maintaining or regaining control of his/her emotions and behaviors

Individual crisis prevention plans are designed to help patients during the earliest stages of distress or escalation before a crisis erupts; help patients identify practicable coping strategies; help staff plan ahead and know what to do with each person if a problem arises; and help staff use interventions that reduce risk and trauma to individuals. These plans often have at least 3 distinct sections which articulate triggers, early warning signs and coping strategies. The plans should encourage creativity, and should be individualized to each patient’s needs, linked to any personal history of trauma, and tailored to environmental resources. In determining the appropriate

intervention for a specific patient in response to an emergency situation which may warrant seclusion or restraint, any preferences or recommendations provided by the patient in the individual crisis prevention plan should be considered.

After it is developed, a copy of the individual crisis prevention plan should be given to the patient and routinely reviewed and updated throughout his/her inpatient admission when changes are warranted. Once the specific coping strategies are identified, they should be incorporated into the patient's individual crisis prevention plan. To provide an opportunity for the patient to build proficiency and increase the probability that they will be effective during times of crisis, the patient should be given an opportunity to "practice" the identified coping strategies at times when he/she is not in crisis.

It is also important for facilities to develop a mechanism to be sure that all staff on all shifts, as well as floating staff, are aware of the patients' individual crisis prevention plans, for those patients that have them. These plans should be attached to the patient's treatment plan and appear in condensed form which is readily accessible by staff. The information can also be included in other places where patient alerts are noted.

### **Best Practice Guidance - What are "Triggers"?**

"Triggers" are situations that may contribute to crisis for the patient under review (e.g., not being listened to, lack of privacy, feeling lonely, being teased, feeling pressured, people yelling, being touched, being isolated, loud noises, arguments, or not having control). For patients who have experienced previous trauma in their lives, triggers may be sights, sounds or smells that remind the person of their previous trauma or cause the person to re-experience the anxiety or other emotions experienced during that traumatic event.

The following are examples of questions that might be utilized, as appropriate, to help articulate triggers:

- "What behaviors, situations or circumstances upset you?"
- "What makes you feel scared, unsafe, upset or angry and could cause you to go into crisis?"

### **Best Practice Guidance – What are "Early Warning Signs?"**

"Early warning signs" are behaviors that a patient displays which indicate he or she may be upset or losing behavioral control (e.g., restlessness, agitation, pacing, shortness of breath, or sweating). The following are examples of questions that might be utilized, as appropriate, to help articulate early warning signs:

- "What behaviors might you display as a result of what you are feeling, or what might you or others notice just before you lose control?"
- "What subtle cues may you exhibit that indicate you are upset, frightened or angry?"
- "What are some things that you might say or do that would indicate that something was wrong?"

## **Best Practice Guidance – What are “Coping Strategies?”**

“Coping strategies” are the patient’s preferred strategies for managing and minimizing stress. (e.g., time away from a stressful situation, going for a walk, talking to someone who will listen, lying down, working out, or listening to peaceful music). The following are examples of questions that might be utilized, as appropriate, to help articulate coping strategies:

- “What techniques, methods or tools help you maintain control of your behavior and thus prevent crisis situations, and what methods help you regain control when you are experiencing loss of control?”
- “What are some things that help you calm yourself when you start to get upset?”
- “Are you able to communicate with staff when you are having a hard time? If not, what can staff do at these moments to help, essentially what can staff do to assist you?”
- “What does not help when you are upset; moreover, what should staff not do or what actions should staff avoid?”
- “Would you like your family to play a role when you are having trouble controlling your behavior? Is there anyone else you would like to have involved?”
- “What medications do you prefer (including dosages if known)? Do you prefer medication by mouth or by injection? Would it be helpful if someone held your hands and did not restrain your body?”
- “We will do our very best to avoid ever placing our hands on you without your permission, but as a last resort in a crisis situation, if you are unable to maintain control and there is an imminent potential for you or others to be injured, which intervention do you feel would be less traumatic to you - seclusion or a particular form of restraint?”
- “If seclusion or restraint is used as a last resort, do you want us to notify your family or a patient advocate of your choice?”

### **(5) Orders for the use of restraint or seclusion:**

In accordance with New York State Mental Hygiene Law Section 33.04, orders for restraint and seclusion must be in writing and signed by a physician. Such orders must never be written as a standing order or on an as needed (PRN) basis. The ongoing authorization for restraint and seclusion is not permitted. Each episode of restraint and seclusion must be initiated in accordance with the order of a physician, based on a personal examination of the patient that includes an evaluation of the patient’s physical and psychological condition. If a patient was recently released from restraint or seclusion, and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order is required. Staff cannot discontinue a restraint or seclusion order, and then re-start it under the same order. This would constitute a PRN order. A “trial release” constitutes a PRN use of restraint or seclusion, and therefore is not permitted by these regulations.

When a staff member ends an ordered restraint or seclusion intervention, the staff member has no authority to reinstitute the intervention without a new order. A temporary, directly-supervised release, however, that occurs for the purpose of caring for a patient’s needs (e.g. toileting, feeding, or range of motion exercises) is not considered a discontinuation of the restraint or seclusion intervention. As long as the patient remains under direct staff supervision, the restraint is not

considered to be discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.

The use of PRN orders for drugs or medication is only prohibited when a drug or medication is being used as a restraint. A drug or medication is deemed to be a restraint only if it is not a standard treatment or dosage for the patient's condition, and the drug or medication is a restriction to manage the patient's behavior or restricts the patient's freedom of movement. Using a drug to restrain the patient for staff convenience is expressly prohibited.

An exception to this is permitted for repetitive self-mutilating behavior. If a patient is diagnosed with a chronic medical or psychiatric condition, such as Lesch-Nyhan Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical and psychiatric conditions, the specific requirements (1 hour face-to-face evaluation, time limited orders, and evaluation every 24 hours before renewal of the order) for the management of violent behavior do not apply. However, the patient must still be continuously monitored in accordance with all other restraint requirements.

Patients of all ages are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior. Therefore, in every case where restraint or seclusion is used, the requirement that the intervention be ended at the earliest possible time applies to all uses of restraint or seclusion. Each written order for restraint or seclusion shall be no more than 4 hours for adults; 1 hour for children and adolescents ages 9 to 17; and 30 minutes for children under 9, with the following exceptions:

- For manual restraint, orders must be limited in duration to 30 minutes for patients of any age. In every case, the use of manual restraint must be limited to the duration of the emergency situation, regardless of the length of the order. Staff must be made aware that a prolonged struggle can produce what is called a "catecholamine crisis," or "adrenergic storm." These conditions can occur to either or both the patient or staff, and the results could be fatal. ***Extreme caution should be exercised during episodes of manual restraint lasting more than 10 minutes, to ensure the health and safety of all involved.***
- If an episode of mechanical restraint or seclusion has exceeded 2 hours for adults, 1 hour for children and adolescents ages 9 to 17, or 30 minutes for children under age 9, and it is expected that restraint or seclusion will be required beyond such time periods, the facility's clinical medical director or director of psychiatry, or his/her designee, must be notified and consulted.

### **Best Practice Guidance - "Witnessing"**

Recognizing that restraint and seclusion are counterintuitive to recovery and hope, the New York State Office of Mental Health has taken a pro-active approach that emphasizes the use of alternatives to restrictive interventions and the employment of evidence-based strategies to create violence and coercion-free cultures. There are many questions regarding the efficacy of seclusion and restraint as treatment interventions for maintaining safety in inpatient and residential psychiatric programs. Oversight groups such as the Joint Commission have encouraged

providers of psychiatric services to reduce or eliminate restraint and seclusion and to develop effective treatment alternatives. Consumer advocacy groups and the National Association of State Mental Health Program Directors (NASMHPD) have stated concerns regarding the dangers and deleterious effects of these restrictive interventions and have recommended against their use.

With this said, each provider of services authorized to utilize restraint and seclusion is strongly encouraged to take the necessary steps to create a violence and coercion-free environment and to significantly reduce the use and duration of restraint and seclusion by employing alternative strategies. The 4 hour maximum time limit for orders of restraint or seclusion, which is permitted under New York law and federal regulations, is nonetheless clearly inconsistent with this goal. Involving the facility clinical director or director of psychiatry in decisions to continue restraint or seclusion for longer than 2 hours for adults, 1 hour for children or adolescents ages 9 to 17, and 30 minutes for children under the age of 9, (i.e., “witnessing”) is more in concert with this initiative, and thus is required by these regulations. “Witnessing” by leadership sends a very clear message that restraint and seclusion beyond these time frames is a very serious matter, and should be extremely rare occurrences.

Though not required under law or regulations, developing a policy and practice to require a new assessment of the patient and a new order to continue restraint or seclusion beyond these durations would be considered best practice and commendable.

The regulations identify the maximum time limits on the length of each order for restraint or seclusion, based on age. The physician has the discretion to write the order for a shorter length of time. The length of order requirement identifies critical points at which there is mandatory contact with a physician responsible for the care of the patient. In addition, the time limits do not dictate how long a patient should remain in restraint or seclusion. Staff are expected to continuously assess and monitor the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Staff should be continually attempting positive therapeutic interventions to assist the person being restrained or secluded to attain the behavioral criteria for release.

Restraint or seclusion may only be employed while the unsafe situation continues and the presence of imminent danger remains. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued. The regulations explicitly state that the intervention must be ended at the earliest possible time, regardless of the length of time identified in the order. For example, if a patient’s behavior is no longer violent or self-destructive 20 minutes after the intervention is initiated, then the restraint or seclusion must be discontinued, even if the order was given for up to 1 hour. If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion.

At the end of the time frame, if the continued use of restraint or seclusion to manage violent or self-destructive behavior is deemed necessary based on an individualized patient assessment, another order is required. When the original order is about to expire, a registered nurse must contact the physician, report the results of his or her most recent assessment and request that the original order be renewed (not to exceed the time limits established in the regulations). Whether or not an onsite assessment is necessary prior to renewing the order is left to the discretion of the physician in conjunction with a discussion with the registered nurse who is overseeing the care of the patient.

Each written order for restraint and seclusion must include documentation supporting its reasons for issuance, with specific identification of the actual behaviors involved; general characterizations of behavior shall not suffice to fulfill this requirement. The order must include criteria for early release, which must reasonably be made known to the patient, and which permit staff to make objective appraisals as to when an attempt can be made to safely release the patient. Clinicians should be adept at identifying various behaviors and symptoms, and thus be able to readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking clinicians to act based on an evaluation of the patient's behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs.

**(6) Initiation in the absence of a physician:**

Restraint or seclusion may be initiated in the absence of a physician's written order only in situations where the patient presents an immediate danger to self or others and a physician is not immediately available to examine the patient, provided, however, that the restraint or seclusion must be initiated at the direction of a registered nurse, nurse practitioner, or physician's assistant who has been authorized by the facility to approve the use of restraint or seclusion in the absence of a physician or, in the absence of the nurse, nurse practitioner, or physician's assistant at the direction of the senior staff member authorized in facility policy to initiate restraint or seclusion in the absence of such person, consistent with the following procedures:

- The nurse, nurse practitioner, or physician's assistant shall cause a physician to be immediately summoned and shall record the time of the call and the person contacted;
- If, when contacted, the physician cannot be on the ward, unit, or wing within 5 minutes, he/she may issue a telephone order to initiate restraint or seclusion to a registered nurse, nurse practitioner, or physician's assistant. It is the expectation that telephone orders to initiate restraint and seclusion will be issued sparingly. The nurse, nurse practitioner or physician's assistant will complete a telephone order and must note the time of the call, the name of the person making the call, the name of the physician who gave the order, and the name of the person or persons who initiated the restraint or seclusion.
- The physician who ordered initiation of the restrictive intervention via telephone order must authenticate the order in writing and assess the situation within 20 minutes. If the physician does not arrive within 30 minutes of being summoned, the nurse, nurse practitioner or physician's assistant shall record any such delay in the patient's clinical record and also place into the patient's clinical record a written description of the facts justifying the emergency intervention, which shall specify the nature of the intervention and any conditions for maintaining it until the arrival of the physician, the reasons why less restrictive forms of restraint or seclusion were not used, and a description of the steps taken to ensure the patient's comfort and safety;
- Pending the arrival of the physician the patient shall be kept under constant supervision;
- Upon arrival, but in no event later than 1 hour after the initiation of the intervention, such physician must immediately conduct a face-to-face examination of the patient, in accordance with applicable federal and state regulations, to evaluate the patient's

immediate situation; the patient's reaction to the intervention; the patient's medical and behavioral condition; and the need to continue or terminate the restraint or seclusion.

- If the physician is not on site after being contacted within 20 minutes, the physician shall place in the clinical record an explanation for any delay.
- Mechanical restraint or seclusion should not be applied for longer than 30 minutes without a written authenticated order of a physician; and in no event should mechanical restraint or seclusion be applied for longer than 1 hour without a written authenticated order of a physician.

## **(7) Assessment and Monitoring:**

Ongoing assessment and monitoring of a patient's condition by a physician, registered nurse or other trained and competent staff is crucial for prevention of patient injury or death, as well as ensuring that the use of restraint or seclusion is discontinued at the earliest possible time. Facility policies are expected to guide staff in determining appropriate intervals to ensure continuous assessment and monitoring of a patient in restraint or seclusion to ensure his or her physical safety and condition. In addition, facility policies should address the assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive function, skin integrity, etc.), and provide for nutritional needs, range of motion exercises, and mental status and neurological evaluations, consistent with the following:

- **Assessment.** An assessment of the patient's condition must be made at least once every 30 minutes, (or more frequently if so directed by the physician) after the initiation of restraint or seclusion. This assessment must be made by a registered professional nurse, nurse practitioner, or physician's assistant who is responsible for the care of the patient and who has been trained, and has demonstrated competency, in the use of restraint and seclusion. However, as a matter of best practice, it is recommended that a staff member who is trained and competent in the use of seclusion and restraint should assess the patient at the initiation of restraint or seclusion, at least every 15 minutes thereafter, and at any other time that it appears the patient is ready to be released, provided, however, that assessments with respect to the physical condition of a patient undergoing drug used as a restraint may be done more frequently in accordance with facility policy. Such assessment must include an assessment of the feasibility of releasing the patient from restraint or seclusion, including specific descriptions of the patient's behavior and the reasons for not releasing the patient from restraint or seclusion.

### **Best Practice Guidance – The Post-Restraint/Seclusion “To Do” List**

Immediately after a patient has been placed in restraints or seclusion, the following steps are strongly encouraged:

- both patient's and staff members' immediate needs should be assessed (e.g., physical well-being, psychological comfort and patient's right to privacy);
- steps that need to be taken to return to the pre-crisis milieu should be identified;
- communication regarding the event should take place among the administration, unit staff, the family and the patient;



- steps should be commenced to begin to evaluate the need for emotional support, including, if necessary, treatment of trauma, for the patient, witnesses/observers and the staff involved; and if immediately indicated, the patient's treatment or individual crisis plan should be modified.
- **Monitoring.** Whenever a patient is restrained or secluded, a staff person shall be specifically assigned to continuously monitor such person one-on-one. The staff person conducting such monitoring may be immediately outside a space in which a person is being secluded or restrained provided, that the staff person is in full view of the patient; and the staff person is able at all times to observe the patient and to have immediate physical access to the patient in order to respond to any emergency situation. The facility is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety.

The staff person should monitor a patient in restraint by being situated so that the staff person is able to hear and be heard by the patient and visually observe the patient at all times. Staff must continually assist and support the patient, including monitoring physical and psychological status and comfort, body alignment, and circulation. It is also expected that staff will continue appropriate interventions designed to calm the patient throughout the episode of restraint or seclusion, and should maintain a log of the patient's specific behavior with respect to the early release criteria established in the physician's order.

Facilities have flexibility in determining which staff performs the patient assessment and monitoring. This determination must be made in accordance with the practitioner's scope of clinical practice under New York State law. For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, other trained and competent staff may perform certain components of monitoring (e.g., checking the patient's vital signs, hydration and circulation, the patient's level of distress and agitation, or skin integrity) and may also provide for general care needs (e.g., eating, hydration, toileting and range of motion exercises). The regulations require that staff must be trained and able to demonstrate competency in the performance of these actions. When a patient is in a non-ambulatory mechanical restraint and under constant observation, any preferences expressed by him or her of the observing staff person should be honored when practicable and clinically appropriate.

**(8) Release:**

Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued. At no time shall the patient be kept in restraint or seclusion without a written order by a physician for a period exceeding 1 hour; however, it must be noted that it is the position of the federal Centers for Medicare and Medicaid Services that keeping a patient in restraint or seclusion beyond a period of 30 minutes is problematic. It should be noted that when a person is asleep, the unsafe situation has ended.

**(9) Documentation:**

Documentation of episodes of restraint and/or seclusion must include a description of the patient's behavior and the intervention used; the rationale for the use of restraint and/or seclusion; and the patient's response to the use of restraint and/or seclusion.

## **(10) Post-Event Analysis and Debriefing Activities:**

A facility must ensure that a post-event analysis, including debriefing activities, occur after each episode of restraint or seclusion in order to determine what led to the incident, what might have been prevented or curtailed it, and how to prevent future episodes. The scope and depth of the debriefing activities should be commensurate with the nature and duration of the intervention utilized, provided requirements established by the Centers for Medicare and Medicaid Services or the Joint Commission, when applicable, are met.

Information obtained from debriefing activities should be used in developing the post event analysis. Debriefing procedures must be identified in facility policies, and should include both staff and patient debriefing activities.

Documentation of all debriefing activities should follow standard protocols, be consistent with national standards, and should be included in the clinical record, for use in treatment planning, revision of the individual crisis prevention plan (or similar document), and ongoing restraint and seclusion prevention efforts.

### **Best Practice Guidance - Staff Debriefing Activities**

Supervisors and staff involved in an episode of restraint/seclusion must convene a debriefing, as soon as practicable after the event, which should include:

- identification of what led to the incident;
- assessment of alternative interventions that may have avoided the use of restraint or seclusion;
- determination of whether the person's physical and psychological needs and right to privacy were appropriately addressed;
- consideration of counseling or treatment for the involved person and staff for any emotional or physical trauma that may have resulted from the event;
- consideration of whether a patient's legally authorized representative (if any), family members, or others should be notified of and/or involved in debriefing activities or offered counseling, consistent with applicable confidentiality laws;
- identification of any environmental precipitants of the restraint or seclusion episode;
- identification of needed refinements in the individual's plan of care or additional assessments to better understand the factors underlying the behavioral problem related to the event
- consideration of whether additional supervision or training should be provided to the staff involved in the event;
- consideration of whether the event should be referred for senior administrative or clinical staff review.

### **What questions might be asked?**

1. What were the first signs that a crisis might be developing?
2. What de-escalation techniques were used?
3. What worked and what did not?
4. What could you do differently next time?
5. How could seclusion or restraint be avoided in this situation in the future?
6. What emotional impact does putting someone in restraints have on you?

7. What was your emotional state at the time of the escalation?

### **Best Practice Guidance - Patient Debriefing Activities**

As clinically appropriate, patient debriefing activities should take place as soon as possible (ideally, within 24 hours) after a patient's release from restraint or seclusion. The patient should be asked to comment on the episode, with respect to the circumstances leading up to it, actions of staff or others that may have helped to prevent it, the specific intervention used, and any physical or psychological effects he or she may be experiencing from the restraint or seclusion. Debriefing activities should be documented and included in the clinical record, to be used in treatment planning, revision of the individual crisis prevention plan (or similar document), and ongoing restraint and seclusion prevention efforts.

#### **What questions might be asked?**

1. How can we better understand what you need, or needed?
2. What upset you most?
3. What did we do that was helpful?
4. What did we do that got in the way?
5. What can we do better next time?
6. Is there anything that you would do differently?

### **Best Practice Guidance – Post Event Analysis**

The focus of a post-event analysis should conceptually focus on the following inquiries:

1. Had a treatment environment been created where conflict was minimized (or not)?
2. Could the trigger for conflict (disease, personal, environmental) have been prevented (or not)?
3. Did staff notice and respond to events (or not)?
4. Was there an Individual Crisis Prevention Plan, was it followed, and was it useful?
5. Did the interaction/intervention occur at the earliest opportunity?
6. Did staff choose an effective intervention (or not)?
7. If the intervention was unsuccessful was another chosen (or not)?
8. Were all pertinent members of the treatment team involved in the de-escalation process (or not)?
9. Did staff order seclusion or restraint only in response to imminent danger (or not)?
10. Was seclusion or restraint applied safely (or not)?
11. Was the individual monitored safely (or not)?
12. Was individual released as soon as behavioral release criteria were met (or not)?
13. Did immediate post-acute event activities occur (or not)?

### **(11) Education and training:**

Facilities are required to provide a safe environment for patients in their care. When restraint or seclusion techniques are used, patients are placed at a higher risk of injury or even death. Facilities must require appropriate staff (all staff who apply restraint or seclusion, monitor access or provide

care for a patient in restraint or seclusion) to receive education and training in the use of first aid techniques, as well as training and certification in the use of cardiopulmonary resuscitation.

Facilities are not required to use any particular recognized first aid course. Additionally, such courses may not adequately address the immediate interventions, the “first aid” that needs to be rendered to a restrained or secluded patient who is in distress or injured. The goal is for staff to be able to render the appropriate “first aid” required if a restrained or secluded patient is in distress or injured. Facility staff need to assess their patient population and identify likely scenarios, develop a first aid training that addresses these scenarios, and provide that “first aid” training to all staff that care for restrained or secluded patients.

In addition, all staff who have direct patient contact must have ongoing education and training, and must demonstrate competence, in the 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 restraints or seclusion. The Office of Mental Health will make available information about training and education programs that have been approved by the Office for this purpose.

## **(12) Policies and procedures:**

Facilities which are authorized to utilize restraint or seclusion for purposes of managing violent or self-destructive behavior must have policies which clearly articulate restraint reduction as an organizational value, set forth the organization’s intent to advance positive behavior management and restraint reduction efforts, and specify the conditions under which restraint and seclusion shall be used, and the procedures for the initiation of such use to manage violent, aggressive behavior that places the patient or others in danger.

### **Best Practice Guidance – Policies and Procedures**

Facility policies and procedures should:

- conform with the requirements set forth in federal and state regulations;
- encourage development and documented use of an individual crisis prevention plan, individualized calming plan, or similar document
- identify how patients will be informed of behavior criteria for the initiation and discontinuation of restraint and seclusion;
- specify who can initiate restraints or seclusion in an emergency prior to the receipt of a physician’s written order, in accordance with Section 33.04 of the Mental Hygiene Law;
- identify how it will be ensured that staff are trained and competent in the safe and minimal use of restraint and seclusion;
- identify and address the need to prevent obstruction of airways during restraint;
- identify how it will be ensured that staff who are assigned monitoring duties of persons in restraint and/or seclusion are competent to assess physical and psychological signs of distress;
- address frequencies of assessment; assessment content, including but not limited to vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity; and provide for nutritional and elimination needs;

- address family notification of the initiation of restraint or seclusion, if the patient has granted permission for such notification and consistent with federal and state confidentiality laws and regulations;
- include procedures for a post-event analysis, including debriefing of the staff and debriefing of the patient;
- provide for patient and family education on restraint and seclusion, and patient education on coping skills and managing aggression, which may be part of a facility or program's overall education policy; and
- ensure that staff are sensitized to the experience of being restrained or secluded.

**(13) Reporting.**

The use of restraint and/or seclusion shall be reported to the Office of Mental Health as, and in a format, specified by the Office, including, but not limited to rate of restraint or seclusion use client injury rates related to restraint; and staff injury rates related to restraint. To implement these requirements:

- State operated programs and RTFs shall continue to report restraint and seclusion data in NIMRS, in the same frequency and format as has been used prior to the promulgation of the regulations.
- Article 28 and 31 hospitals shall continue to report data to The Joint Commission (TJC) in the format and frequency designated by TJC. Hospital-Based Inpatient Psychiatric Services (HBIPS) Measure Information Forms for HBIPS-2 (Restraint) and HBIPS-3 (Seclusion):

<https://manual.jointcommission.org/releases/TJC2014A/MIF0117.html>  
<https://manual.jointcommission.org/releases/TJC2014A/MIF0118.html>

- CPEPs have not previously reported restraint and seclusion data to an oversight agency. Guidance with respect to CPEP restraint and seclusion reporting to OMH is pending; CPEP providers shall be required to report at such time as this guidance document is revised to identify requisite form, format, and frequency.

In addition, any death that occurs while a patient is restrained or in seclusion to manage violent or self-destructive behavior, or where it is reasonable to assume that a patient's death is a result of such restraint or seclusion, or as otherwise set forth in applicable federal regulations, must be reported to the federal Centers for Medicare and Medicaid Services.