



PERSON-CENTERED BEHAVIORAL INTERVENTION
Revised Proposed regulations

THE ADDITION OF A NEW 14 NYCRR SECTION 633.16
AND AMENDMENT OF 14 NYCRR PARTS 81, 624, 633 and 681
Comments due: Friday, November 16, 2012

- **A new section 633.16 is added to Part 633 as follows:**

633.16 Person-Centered Behavioral Intervention.

(a) *Applicability.*

(1) This section applies to:

- (i) all residential facilities certified or operated by OPWDD, including family care homes;
- (ii) all facilities certified by OPWDD, except:
 - (a) free standing respite;
 - (b) clinic treatment facilities (see Part 679 of this Title); and
 - (c) diagnostic and research clinics (see Part 676 of this Title);
- (iii) day habilitation services (whether or not provided in a certified facility);
- (iv) prevocational services (whether or not provided in a certified facility); and
- (v) community habilitation (both hourly and Phase II).

(2) The requirements of this section concerning the use of medication only apply to residential facilities which are certified or operated by OPWDD, including family care homes.

(3) Intermediate Care Facilities (see Part 681 of this Title) should note that they must also comply with the requirements of 42 CFR 483. In some instances, these federal requirements are more stringent than the requirements of this section.

Note: Language in the new Section 633.16 is all new material but is not underlined. Otherwise, new material is underlined; deleted material is in [brackets].

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- (4) This section is effective on the effective date.
 - (5) The requirements of this section are applicable for new behavior support plans (not revisions or renewals of previously existing plans) 60 days after the effective date of this section. This includes provisions for obtaining informed consent for the plans, if required.
 - (6) The requirements of this section are applicable for behavior support plans which are revisions or renewals of previously existing plans one year after the date specified in paragraph (5) of this subdivision. This includes provisions for obtaining informed consent for the plans, if required.
- (b) *Definitions.* As used in this section.
- (1) *Approve/Approving.* The determination by the behavior plan/human rights committee established pursuant to subdivision (f) of this section, that it has authorized the implementation of a proposed behavior support plan which incorporates restrictive/intrusive interventions and/or limitations on a person's rights as specified in paragraph (f)(3) of this section.
 - (2) *Assessment, functional behavioral.* A process intended to: identify and operationally describe challenging behavior(s); identify the function(s) or purpose(s) for challenging behavior; and to identify the specific environmental stimuli or conditions that are maintaining the challenging behavior(s). (See subdivision (d).)
 - (3) *Aversive conditioning.* See conditioning, aversive.
 - (4) *Behavior, Challenging.* Challenging behavior may take many forms, including undesirable and/or socially unacceptable behavior that interferes with the acquisition or use of desired skills or knowledge, interferes with the performance of everyday activities, undermines the potential for increased self-determination and independence, interferes with the rights of others, disrupts social functioning, and/or causes injury to self or others. These may include psychiatric symptoms or overt reactions to symptoms that may be expressed as challenging behaviors (e.g., manic behavior, aggressive behavior, compulsive behavior or verbal threats based on paranoid beliefs or perceptions).
 - (5) *Behavior support plan.* See plan, behavior support.
 - (6) *Behavior, modifying/managing challenging.* "Modifying/managing" means using behavioral interventions and/or other psychological treatment approaches that are expected to result in the prevention or elimination of challenging behavior, foster the development

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of new adaptive (replacement) behaviors, increase or maximize existing adaptive behaviors, or minimize undesirable behaviors.

- (7) *Behavior, controlling challenging.* "Controlling" means using interventions in a behavioral event to prevent or contain challenging behavior, so as to constrain, restrain or otherwise limit or restrict that behavior for the protection of the person and/or others.
- (8) *Behavioral Intervention Specialist (See Specialist, Behavioral Intervention.)*
- (9) *Committee, behavior plan/human rights.* A committee which has the responsibility to protect the rights of persons whose behavior support plan incorporates the use of any restrictive/intrusive intervention and/or limitation on a person's rights in order to prevent, manage and/or control challenging behavior, and which exercises this responsibility through the process of reviewing and approving proposed behavior support plans.
- (10) *Committee, informed consent.* A committee which has the authority to give informed consent for a behavior support plan incorporating the use of any restrictive/intrusive intervention, when the individual lacks capacity to consent and there is no other authorized surrogate available (except for a court). (See subdivision (g) of this section.)
- (11) *Conditioning, aversive.* The contingent application of a physical stimulus or device to a person's body or senses in order to modify or change behavior. Such a stimulus or device must be reasonably considered to be uncomfortable, painful, or noxious to the person when applied. Examples of such stimuli may include, but are not limited to: water and other mists or sprays, noxious odors (e.g., ammonia), noxious tastes (e.g., hot sauce), corporal punishment (e.g., slapping, spanking, hitting, or pinching), air blasts, blindfolds, white noise helmets, and electric skin shock (See paragraph (15) of this subdivision).
- (12) *Conflict of interest.* See Interest, conflict of.
- (13) *Consent, informed.*
 - (i) For the purposes of this section, *informed consent* shall mean the effective knowing consent by a person (or his/her legally authorized surrogate) with sufficient capacity to consent and so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. Such consent shall be in writing, except in the case of the short-term use of medication pursuant to subparagraph (j)(5)(v) of this section and as provided in paragraph (g)(1) of this section.
 - (ii) The basic elements of information necessary to such informed consent include:

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- (a) a fair explanation to the person or surrogate of the procedures to be followed, and their purposes;
 - (b) a description of any potential discomforts and risks which may reasonably be expected;
 - (c) a description of any benefits to the participant which may reasonably be expected;
 - (d) a disclosure of appropriate alternative procedures, if any; and
 - (e) an instruction that the person or surrogate is free to withdraw his or her consent at any time without prejudice.
- (iii) No informed consent shall include any language through which the person or surrogate waives, or appears to waive, any legal right, including the release of any party, institution, agency, or any agents thereof, from liability from negligence.
- (iv) Information about planned interventions must be presented in a manner that permits a knowledgeable evaluation and decision to be made. It must be presented in simple terms, in whatever language the party giving informed consent reads or understands most easily and clearly (e.g., English, Spanish, Mandarin), and in whatever manner he or she understands most easily and clearly (e.g., sign language, communications board, computer assisted technology, Braille). Consent, when given by a surrogate, should only be given if, in doing so, this will be in the person's best interest and takes into consideration, to the extent possible, the person's opinions, beliefs and wishes.
- (14) *Device, mechanical restraining.* Any physical apparatus or equipment used to limit or control challenging behavior. This apparatus or equipment cannot be easily removed by the person and may restrict the free movement, or normal functioning, or normal access to a portion or portions of a person's body, or may totally immobilize a person. (See paragraph (j)(4) for requirements specific to the use of mechanical restraining devices.)
- (15) *Electric skin shock.* The application to a person's body of an electronic skin shock device in an effort to modify or change behavior. Such a device is reasonably considered to be uncomfortable, painful, or noxious to the person when applied. This definition is not applicable to the use of electroconvulsive therapy provided in a hospital setting and used as a treatment for specific psychiatric disorders.
- (16) *Emergency.* A term that describes a situation posing an immediate health or safety risk to the person or to others that is unexpected, unforeseen, or unanticipated, and for which

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procedures have not been specified in a person's behavior support plan to address how the staff is to handle the emergent situation.

- (17) *Functional Behavioral Assessment.* See Assessment, functional behavioral.
- (18) *Guardian.* A party appointed by a court of competent jurisdiction to make or assist a person to make personal and/or financial decisions in situations in which the person is deemed not to have capacity to make those decisions .
- (19) *Immobilize, totally.* The complete curbing of the movement of both arms and both legs, and/or torso through the use of (but not limited to):
 - (i) securing of arms and legs directly to another object (e.g., straps on a chair, papoose board); or
 - (ii) four point restraints.
- (20) *Instructor.* A party employed by OPWDD, or by an agency certified or authorized by OPWDD, who has been approved to teach a curriculum approved by OPWDD on the use of positive behavioral approaches, strategies and/or supports and physical intervention techniques.
- (21) *Instructor-Trainer.* A party employed by OPWDD, or by an agency certified or authorized by OPWDD, who has been approved to teach a curriculum approved by OPWDD on the use of positive behavioral approaches, strategies and/or supports and physical intervention techniques and further certified by OPWDD to train, mentor and certify new Instructors in the teaching and implementation of the training curriculum. An Instructor-Trainer also reviews and/or approves modified physical intervention techniques as necessary.
- (22) *Interest, conflict of.* Any real or perceived financial, personal or other interest, which may impede the impartial discharge of the party's duties.
- (23) *Intervention, physical.* Those intervention techniques, or the adaptations of such, that either include; hands-on techniques that deflect, protect from, or release hits, kicks or grabs by persons receiving services toward others in their environment, or holds of limited duration that may reduce, limit, or restrict an individual's freedom of movement in order to interrupt or control challenging behavior that is posing an immediate health or safety risk to the person or to others. (See paragraph (j)(1) of this section for requirements specific to the use of physical intervention techniques.) There are three categories of physical intervention techniques:
 - (i) protective techniques, which include blocks, deflection strategies and grab releases;

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- (ii) intermediate techniques, which include holds and escorts intended to maintain a person in a standing or seated position to reduce or limit movement, to maintain health and safety, and/or to remove a person from an unsafe location or situation; and
 - (iii) restrictive techniques, which include holds that restrict freedom of movement in order to interrupt or control behavior that is posing an immediate health or safety risk to the person or to others and involve taking a person from a standing position to the floor and holding the person on the floor.
- (24) *Intervention, restrictive/intrusive.* These interventions include the following:
- (i) intermediate and/or restrictive physical intervention techniques (see paragraph (j)(1) of this section);
 - (ii) the use of time-out (exclusionary and non-exclusionary) (see paragraph (j)(3) of this section);
 - (iii) the use of any mechanical restraining device with the intent to modify or control challenging behavior (see paragraph (j)(4) of this section);
 - (iv) the use of medication for the sole purpose of preventing, modifying, or controlling challenging behavior that is not associated with a diagnosed co-occurring psychiatric condition (see paragraph (j)(5) of this section); and
 - (v) other professionally accepted methods to modify or control behavior which are determined by agency/facility policy to be restrictive/intrusive interventions because they impose a risk to a person's protection or encroach unduly on a person's normal activities (e.g., response cost, overcorrection, negative practice, and satiation).

Intervention techniques to facilitate medical/dental exams, procedures, and healthcare activities and to protect individuals and healthcare providers during such exams, procedures and activities are not considered to be restrictive/intrusive interventions.

- (25) *Master Trainer.* A party employed by OPWDD who has been approved to teach a curriculum approved by OPWDD on the use of positive behavioral approaches, strategies and/or supports and physical intervention techniques, and further certified by OPWDD to train and mentor new Instructor-Trainers and Instructors in the teaching and implementation of the training curriculum. The Master Trainer serves in a leadership role overseeing the quality of Instructors, quality and consistency of trainings, and coordinating

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and monitoring implementation of the curriculum.. The Master Trainer also reviews and approves new or modified physical intervention techniques as necessary.

- (26) *Mechanical restraining device.* See device, mechanical restraining.
- (27) *Medication.* For the purposes of this section, a pharmaceutical agent prescribed and used either to prevent, modify, or control challenging behavior, or to treat the symptoms of co-occurring diagnosed psychiatric conditions, by altering thoughts, feelings, mental activities, mood, or behavior. This definition includes medications which are not usually classified as psychotropic, when they are prescribed for their psychotropic effects such as mood stabilization or impulse control. (See paragraph (j)(5)(vi) of this section for requirements specific to the use of medications used to treat a co-occurring psychiatric condition)
- (28) *Plan, behavior support.* A written plan that outlines specific interventions designed to support, develop or increase replacement or alternative behaviors and/or modify or control a person's challenging behavior. The plan is a component of a person's overall plan of services. Agencies may use other equivalent terms for such plans. (See subdivision (e) of this section.)
- (29) *Plan, monitoring.* A plan developed by a Behavioral Intervention Specialist, licensed psychologist, or licensed clinical social worker, which identifies the target symptoms of a diagnosed co-occurring psychiatric disorder which are to be prevented, reduced, or eliminated. The plan shall specify interventions that will be used to address associated challenging behaviors that may occur, and methods by which progress in symptom control and functional improvement will be measured, documented, and reviewed.
- (30) *Restrictive/intrusive intervention.* See intervention, restrictive/intrusive.
- (31) *Senior member of the staff.* See Staff, senior member of the.
- (32) *Specialist, Behavioral Intervention (BIS)*
 - (i) Level 1 BIS. In order for a party to be a Level 1 BIS, the party must:
 - (a) have at least a Master's degree from a program in a clinical and/or treatment field of psychology and have had documented training in assessment techniques and behavioral support plan development; and
 - (b) have at least five (5) years of experience:

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- (i) working directly with individuals with developmental disabilities, including the devising, implementation, and monitoring of behavioral support plans; and/or
 - (ii) providing supervision and training to others in the implementation of behavior support plans.
 - (ii) Level 2 BIS. In order for a party to be a Level 2 BIS, the party must meet the qualifications as outlined in clauses (a), (b), (c) or (d) as follows:
 - (a) The party must:
 - (1) have National board certification in behavior analysis (BCBA); and
 - (2) have a Master's degree in behavior analysis, or a field closely related to clinical or community psychology which is approved by OPWDD review; or
 - (b) The party must:
 - (1) have either:
 - (i) a Master's degree in a clinical or treatment field in psychology, social work, school psychology, or a related human services field; or
 - (ii) a New York State license in Mental Health Counseling; and
 - (2) have or obtain OPWDD-approved specialized training or experience in assessment techniques and behavioral support plan development; and
 - (3) have provided behavioral services for an agency in the OPWDD system continuously since December 31, 2012; or
 - (c) The party must:
 - (1) have a Master's degree in a clinical or treatment field in psychology, social work, school psychology, or a related human services field; and
 - (2) function in the Psychologist I or Psychologist II Civil Service titles of New York State; or

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- (d) The party must:
 - (1) have a Bachelor's degree in a human services field; and
 - (2) have provided behavioral services for an agency in the OPWDD system continuously since December 31, 2012; and
 - (3) either:
 - (i) is actively working toward a Master's degree in an applied area of psychology, social work, or special education; or
 - (ii) completes at least one graduate-level course in an applied health service area of applied psychology, social work, or special education each year.
- (iii) The qualifying Master's degrees referenced in this paragraph, including any degree obtained through an online educational or distance learning program, must have been awarded by a regionally accredited college or university, or one recognized by the NYS Education Department as following acceptable educational practices. If the Master's degree was awarded by an educational institution outside the United States and its territories, the party must provide independent verification of equivalency from one of the approved entities utilized by the NYS Department of Civil Service for educational equivalency reviews.
- (iv) Notwithstanding any other provision of this paragraph, a party may be considered a BIS in the event that OPWDD has approved a waiver of a specific required qualification upon application of a provider (See paragraph (c)(12) of this section.
- (v) In the event that New York State law requires licensure for parties to legally provide any of the services specified in this section, a BIS who does not have the necessary New York State licensure may no longer perform those services.
- (33) *Staff, senior member of the.* As used in this section, that staff member, by whatever title he or she may be known who is designated by the chief executive officer (CEO) as a senior member of the administrative structure of an agency, and as such, may carry out designated responsibilities delegated by the CEO. This may be someone who is responsible for a group of facilities (e.g., Team Leader, residence manager, head of shift, unit supervisor).

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- (34) *Team, program planning.* For the purposes of this section, the program planning team includes at least a licensed psychologist, a licensed clinical social worker, or an Behavioral Intervention Specialist, the person, the service coordinator or party designated with the responsibility for coordinating a person's plan of services, the person's advocate or correspondent (including the Consumer Advisory Board for Willowbrook Class Members that it fully represents), and any other party deemed necessary for identifying a person's behavioral needs and developing an appropriate plan to address those needs (e.g., direct support professional, health care professional). A registered nurse or other medical professional shall be a member of the team when the use of medication is part of the plan.
- (35) *Time-out.* Time-out is a restrictive/intrusive intervention in which a person is temporarily removed from positive reinforcement or denied the opportunity to obtain positive reinforcement *and* during which the person is under constant visual and auditory contact and supervision. Time-out interventions include:
- (i) placing a person in a specific time-out room, commonly referred to as exclusionary time-out;
 - (ii) removing the positively reinforcing environment from the individual, commonly referred to as non-exclusionary time-out.

(See paragraph (j)(3) of this section for requirements specific to the use of time-out.)

(c) *General provisions.*

- (1) Every agency with oversight responsibilities for one or more programs that serve people in need of behavior support plans shall develop behavior intervention policies and procedures that are in conformance with this section.
- (2) All behavioral interventions designed to prevent or modify challenging behaviors shall be in conformance with applicable laws and regulations and agency- specific policies/procedures. Interventions and intervention plans must be individualized and designed for the purpose of enhancing the individual's quality of life, relationships with others, and ability to function as independently as possible. Such interventions shall actively include positive approaches, strategies and/or supports designed to establish or increase the person's adaptive (replacement) behaviors.
- (3) Behavioral interventions shall be designed and implemented for the purpose of developing or increasing adaptive behaviors (a.k.a. replacement behaviors) that support more independent and personally successful living, and eliminating or decreasing the frequency of challenging behaviors, but never employed for the convenience of staff, as a threat, as a

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means of retribution, for disciplinary purposes, or as a substitute for treatment or supervision.

- (4) Positive behavioral approaches, strategies, and supports that are consistent with standards of professional practice shall always be the preferred method for addressing challenging behavior, with the overall goal of increasing the person's repertoire of appropriate behaviors and skills. These positive approaches should include a variety of proactive strategies that may include prevention strategies, setting event strategies, teaching replacement or alternative behaviors such as functional communication and social skills, stress management skills, positive reinforcement, shaping, differential reinforcement procedures, etc.
- (5) OPWDD discourages the use of restrictive/intrusive interventions. General and specific requirements regarding the use of restrictive/intrusive interventions are imposed in order to limit the use of these interventions to those situations when necessary. Unless there is a clear risk to the health or safety of the person or others, or a violation of others' basic personal rights, any restrictive/intrusive intervention or limitation on a person's rights as specified in a behavior support plan shall be employed only after less intrusive or more positive interventions have been tried and have not been sufficiently successful.
- (6) The use of aversive conditioning methods is prohibited.
- (7) There shall be sufficient safeguards and supervision to ensure that the dignity, safety, health, welfare, and civil rights of a person have been adequately protected. No behavior support plan shall:
 - (i) incorporate sleep deprivation as a consequence of challenging behavior; or
 - (ii) deprive a person of a balanced and nutritious diet;
 - (a) meals shall be served at appropriate times and in as normal a manner as possible;
 - (b) the composition or timing of regularly served meals shall not be altered for disciplinary (punishment) purposes, or for the convenience of staff;
 - (c) restrictions of the amount of food or type of diet that a person consumes may be made for clinical reasons, pursuant to documentation by a qualified healthcare professional, which shall specify the clinical justification for the restriction and the time period that such restriction shall be in effect, and which shall be included in the individual's written service plan;

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- (d) nothing in this subparagraph shall be deemed to limit the ability of a facility or agency to adopt policies or procedures to promote the health of each person and a safe and sanitary environment; or
 - (iii) incorporate the use of food such that the form of the food served is altered as a consequence of challenging behavior.
- (8) Additional requirements apply to the use of “restrictive/intrusive interventions.” These interventions include the following:
 - (i) any intermediate and/or restrictive physical intervention techniques (see paragraph (j)(1) of this section);
 - (ii) the use of time-out (exclusionary and non-exclusionary) (see paragraph (j)(3) of this section);
 - (iii) the use of any mechanical restraining device with the intent to modify or control challenging behavior (see paragraph (j)(4) of this section);
 - (iv) the use of medication solely to prevent, modify, or control challenging behavior (see paragraph (j)(5) of this section); and
 - (v) other professionally accepted methods to modify or control behavior which are determined by agency/facility policy to be restrictive/intrusive interventions because they impose a risk to a person’s protection or encroach unduly on a person’s normal activities (e.g., response cost, overcorrection, negative practice, and satiation).
- (9) Additional requirements apply to behavioral interventions which impose a limitation on a person’s rights as specified in section 633.4 of this Part, including behavioral consequences negatively impacting the person’s dignity (see paragraph (j)(2) of this section).
- (10) Any objection to a person’s current or proposed behavior support plan or to a proposed revision of a current plan must be made following the process as outlined in section 633.12 of this Part, except for objections to the use of restrictive/intrusive interventions by the party providing informed consent and objections to medication use by an individual receiving services. (See subdivision (h) of this section.)
- (11) Restrictive/intrusive interventions may not be used in an emergency, except for intermediate and restrictive physical intervention techniques and medication. (See

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paragraphs (j)(1) and (j)(5)). Limitations on a person's rights may also be used in an emergency (see paragraph (j)(2)).

(12) Notwithstanding any other provision of this section, a party lacking the specified credentials may perform the functions of a Level I BIS, Level II BIS, licensed psychologist, or licensed clinical social worker as specified in this section if OPWDD has granted a waiver of a specific required qualification for that particular party. The waiver may limit the functions that may be performed by such party.

(i) OPWDD may approve a waiver upon application of the provider if all of the following conditions are met:

(a) the provider documents that it is unable to employ, or access contractual services from, a party who meets the requirements for a Level 1 BIS, Level 2 BIS, licensed psychologist, or licensed clinical social worker;

(b) the provider is in a rural area; and

(c) the provider has demonstrated a sustained hardship condition concerning its ability to obtain the necessary clinical services.

(ii) In the event that New York State law requires licensure for parties to legally provide any of the services specified in this section, a party performing such services pursuant to a waiver which are inconsistent with the law may no longer perform those services.

(d) *Functional behavioral assessment.*

(1) Prior to the development of a behavior support plan to address challenging behavior that is not solely the result of a diagnosed co-occurring psychiatric disorder, a functional behavioral assessment must be completed by a clinician with training in functional behavior assessment techniques to obtain relevant information for effective intervention planning. A functional behavioral assessment must:

(i) identify/describe the challenging behavior in observable and measurable terms;

(ii) include identification and consideration of the antecedents for the behavior(s);

(iii) identify the contextual factors, including cognitive, environmental, social, physical, medical and/or psychiatric conditions, that create or may contribute to the behavior;

(iv) identify the likely reason or purpose for the challenging behavior;

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- (v) identify the general conditions or probable consequences that may maintain the behavior;
 - (vi) include an evaluation of whether environmental or social alterations, or further assessments to rule out a contextual factor, would serve to reduce or eliminate the behavior(s);
 - (vii) include an evaluation of preferred reinforcers;
 - (viii) consider multiple sources of data including, but not limited to:
 - (a) information gathered through direct observations of the individual;
 - (b) information gathered from interview and/or discussion with the individual, parent/caregiver, and other relevant service providers; and
 - (c) a review of available clinical, medical, behavioral, or other data from the individual's record and other sources;
 - (ix) not be based solely on an individual's documented history of challenging behaviors; and
 - (x) provide a baseline of the challenging behaviors including frequency, duration, intensity and/or latency across settings, activities, people, and times of day.
- (2) In exceptional circumstances (e.g., unexpected admission to a residential program) a behavior support plan may need to be developed or modified primarily on the basis of historical information to assure staff or the family care provider have sufficient tools and safeguards to manage potentially dangerous behaviors of the person who is beginning to receive services. In these cases, a functional behavioral assessment shall be completed within 60 days of admission or the commencement of services.
- (e) *Behavior support plan.*
- (1) Level 1 Behavioral Intervention Specialists (BIS) may develop and/or provide supervision for behavioral support plans or services that do not include restrictive/intrusive interventions. Level 2 BIS may develop behavioral support plans or services that do not include restrictive/intrusive interventions under the supervision of Level 1 BIS. Behavior support plans or services which include restrictive/intrusive interventions may be developed by a Level 1 or a Level 2 BIS under the supervision of a licensed psychologist or licensed clinical social worker (LCSW) (see subparagraph (e)(3)).

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- (2) All behavior support plans must:
- (i) be developed by a BIS, or a licensed psychologist or a licensed clinical social worker with training in behavioral intervention techniques;
 - (ii) be developed in consultation, as clinically appropriate, with the person receiving services and/or other parties who are or will be involved with implementation of the plan;
 - (iii) be developed on the basis of a functional behavioral assessment of the target behavior(s);
 - (iv) include a concrete, specific description of the challenging behavior(s) targeted for intervention;
 - (v) include a hierarchy of evidence-based behavioral approaches, strategies and supports to address the target behavior(s) requiring intervention, with the preferred methods being positive approaches, strategies and supports;
 - (vi) include a personalized plan for actively reinforcing and teaching the person alternative skills and adaptive (replacement) behaviors that will enhance or increase the individual's personal satisfaction, degree of independence, or sense of success;
 - (vii) include the least restrictive or least intrusive methods possible in the behavioral approaches, strategies and supports designed to address any behaviors that may pose an immediate risk to the health or safety of the person or others;
 - (viii) provide a method for collection of positive and negative behavioral data with which treatment progress may be evaluated; and
 - (ix) include a schedule to review the effectiveness of the interventions included in the behavior support plan no less frequently than on a semi-annual basis, including examination of the frequency, duration, and intensity of the challenging behavior(s) as well as the replacement behaviors.
- (3) A behavior support plan which incorporates a restrictive/intrusive intervention and/or a limitation on a person's rights (see paragraph (c)(9) of this section) shall be designed in accordance with the following:

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- (i) Level 1 & Level 2 BIS who develop and/or provide behavior support services to implement behavior support plans which include restrictive/intrusive interventions shall function under the supervision of a licensed psychologist or licensed clinical social worker.
- (ii) A plan that incorporates a restrictive/intrusive intervention and/or a limitation on a person's rights must include the following additional components:
 - (a) a description of the person's behavior that justifies the incorporation of the restrictive/intrusive intervention(s) and/or limitation on a person's rights to maintain or assure health and safety and/or to minimize challenging behavior;
 - (b) a description of all positive, less intrusive, and/or other restrictive/intrusive approaches that have been tried and have not been sufficiently successful prior to the inclusion of the current restrictive/intrusive intervention(s) and/or limitation on a person's rights, and a justification of why the use of less restrictive alternatives would be inappropriate or insufficient to maintain or assure the health or safety or personal rights of the individual or others;
 - (c) designation of the interventions in a hierarchy of implementation, ranging from the most positive or least restrictive/intrusive to the least positive or most restrictive/intrusive, for each challenging behavior being addressed;
 - (d) the criteria to be followed regarding postponement of other activities or services, if necessary and/or applicable (e.g., to prevent the occurrence or recurrence of dangerous or unsafe behavior during such activities);
 - (e) a specific plan to minimize and/or fade the use of each restrictive/intrusive intervention and/or limitation of a person's rights, to eliminate the use of a restrictive/intrusive intervention and/or limitation of a person's rights, and/or transition to the use of a less intrusive, more positive intervention; or, in the case of continuing medication to address challenging behavior, the prescriber's rationale for maintaining medication use;
 - (f) a description of how each use of a restrictive/intrusive intervention and/or limitation on a person's rights is to be documented, including mandated reporting, and
 - (g) a schedule to review and analyze the frequency, duration and/or intensity of use of the restrictive/intrusive intervention(s) and/or limitation on a person's

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rights included in the behavior support plan. This review shall occur no less frequently than on a semi-annual basis. The results of this review must be documented, and the information used to determine if and when revisions to the behavior support plan are needed.

- (iii) A behavior support plan incorporating the use of restrictive physical interventions and/or time-out rooms is prohibited in family care homes and Hourly Community Habilitation. However, a behavior support plan incorporating restrictive physical interventions in Hourly Community Habilitation may be permitted if specifically authorized by OPWDD.
 - (4) Prior to implementation of a behavior support plan which incorporates a limitation on a person's rights and/or a restrictive/intrusive intervention:
 - (i) the plan shall be approved by the behavior plan/human rights committee established pursuant to subdivision (f) of this section; and
 - (ii) written informed consent shall be obtained from the appropriate consent-giver.
 - (5) If a behavior support plan is necessary in more than one service setting, the agency developing such a plan shall consult and coordinate with other service settings, in order to prevent conflicting or inappropriate strategies.
 - (6) If an agency will be using a behavior support plan developed by a different service setting/agency, the agency that developed the plan shall provide documentation to the other service setting/agency regarding current informed consent for the plan and its approval by a behavior plan/human rights committee.
 - (7) Nothing in this subdivision (633.16(e)) shall be construed to prevent the use of physical intervention techniques in an emergency when used in conformance with paragraph (j)(1) of this section.
 - (8) Nothing in this subdivision (633.16(e)) shall be construed to prevent the use of limitations on a person's rights in an emergency when used in conformance with paragraph (j)(2) of this section.
 - (9) Nothing in this subdivision (633.16(e)) shall be construed to prevent the use of medication to modify or control challenging behavior in an emergency when used in conformance with subparagraph (j)(5)(iv) of this section.
- (f) *Behavior plan/human rights committee.*

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- (1) Every agency with oversight responsibilities for one or more programs that serve people in need of behavior support plans that include restrictive/intrusive interventions and/or rights limitations shall establish a behavior plan/human rights committee to protect the rights of persons whose behavior support plans incorporate the use of restrictive/intrusive interventions and/or a limitation on a person's rights. It may be a separate committee created solely for the purpose of meeting the requirements of this section, or it may be part of another committee. An agency is not required to have a behavior plan/human rights committee if:
 - (i) No individual served is in need of a behavior support plan that includes a restrictive/intrusive intervention other than medication to treat a co-occurring diagnosed psychiatric condition; and
 - (ii) No individual served is in need of a behavior support plan that includes a limitation on the person's rights.
- (2) Agencies shall create their own behavior plan/human rights committee or may coordinate with other agencies in the creation of a shared behavior plan/human rights committee.
- (3) Prior to the implementation of the proposed behavior support plans, the committee shall approve or refuse to approve, in writing, proposed plans which contain a limitation on a person's rights (see paragraph (c)(9) of this section) and/or utilize one or more restrictive/intrusive interventions specified in paragraph (c)(8) of this section, except for plans in which medication is used solely for the treatment of a co-occurring diagnosed psychiatric condition. The term "psychiatric condition" means those psychiatric conditions which are recognized as such by the American Psychiatric Association or World Health Organization. For the purposes of this section, the term "co-occurring psychiatric condition" does not refer to the following: mental retardation, learning disorders, motor skills disorders, communication disorders, pervasive developmental disorders, attention-deficit and disruptive behavior disorders, and impulse control disorders.
- (4) The committee must review the behavior support plans identified in paragraph (3) of this subdivision to verify that all required components are included (see subdivision (e) of this section).
- (5) The committee chairperson must verify that:
 - (i) the proposed behavior support plans presented to the committee are approved for a time period not to exceed one year and are based on the needs of the person; and
 - (ii) written informed consent is obtained *prior to the implementation* of the approved behavior support plan. If written informed consent cannot be obtained within a

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reasonable period of time prior to the initiation or continuance of a plan, *verbal consent* may be accepted only for the period of time before written informed consent can be reasonably obtained. Verbal consent must be witnessed by two members of the staff, and documented in the person's record. This verbal consent is valid for a period of up to 45 days and may not be renewed.

- (6) The committee must specifically approve (or refuse to approve):
 - (i) the use of a mechanical restraining device that is not commercially available or is not designed for human use (e.g., modification of a commercially available device) pursuant to subclause (j)(4)(ii)(a)(2) of this section; and
 - (ii) modification of intermediate and restrictive physical intervention techniques, and new intermediate and restrictive physical intervention techniques, consistent with the provisions of subparagraph (j)(1)(iii) of this section.
- (7) The committee shall review and make suggestions to the agency's management and/or governing body about its policies, practices, and programs as they relate to topics addressed by this section.
- (8) Behavior plan/human rights committee membership.
 - (i) A behavior plan/human rights committee must have a minimum of four members including:
 - (a) a licensed psychologist or a Behavioral Intervention Specialist, with training in assessment techniques and behavioral support plan development;
 - (b) a clinician, currently licensed, certified, or registered in New York State as one of the following: social worker, physician, physician assistant, nurse practitioner, registered nurse, speech pathologist, occupational therapist, physical therapist, or pharmacist; and
 - (c) an additional party, preferably with no ownership, employment relationship, or other interest in the agency. This party may be, but is not limited to:
 - (1) someone charged with the responsibility for advocating for a person's rights (e.g., an ombudsperson, a volunteer, or an advocacy organization representative); or
 - (2) someone with a developmental disability, or a guardian or family member of someone with a developmental disability.

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- (ii) A committee member must recuse himself/herself from reviewing a plan for a person for whom he/she is actively involved in the delivery of services.
 - (iii) The committee must have a minimum of three members present to proceed with its deliberations.
- (g) *Informed consent.*
- (1) Written informed consent shall be obtained in accordance with this subdivision.
 - (i) Written informed consent is required prior to implementation any time that a restrictive/intrusive intervention is included in a behavior support plan to modify or control challenging behavior. However, if written informed consent cannot be obtained within a reasonable period of time prior to the initiation or continuance of a plan, *verbal consent* may be accepted only for the period of time before written informed consent can be reasonably obtained. Verbal consent must be witnessed by two members of the staff, and documented in the person's record. This verbal consent is valid for a period of up to 45 days and may not be renewed.
 - (ii) Written informed consent is also required for short-term use of medication when there is no behavior support plan. If it is necessary for the medication to be administered before written informed consent can be reasonably obtained, verbal consent may be accepted for only the period of time before written informed consent can be reasonably obtained, but no longer than 45 days. Verbal consent must be witnessed by two members of the staff and documented in the person's record.
 - (2) Written informed consent shall be documented in a person's clinical record.
 - (3) Written informed consent obtained in accordance with this subdivision shall have a maximum duration of one year.
 - (4) The agency shall ensure, in every case, that the person (or surrogate consent giver) be personally afforded an appropriate, clear explanation of the proposed plan.
 - (5) When an emergency exists, restrictive/intrusive interventions may be applied to a person of any age without seeking informed consent if such use is permitted in accordance with this section.
 - (6) Informed consent for behavior support plans that include restrictive/intrusive interventions shall be obtained as follows:

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- (i) If a person is less than 18 years of age, consent shall be obtained from one of the surrogates listed, in the order stated:
 - (a) a guardian lawfully authorized to give such consent;
 - (b) an actively involved (see section 633.99) spouse;
 - (c) a parent;
 - (d) an actively involved adult sibling (see section 633.99);
 - (e) an actively involved adult family member (see section 633.99);
 - (f) a local commissioner of social services with custody of the person pursuant to the social services law or family court (if applicable); or
 - (g) an informed consent committee or a court of competent jurisdiction (see paragraph (8) of this subdivision).

- (ii) If a person is 18 years of age or older and has capacity to give informed consent, the plan shall be initiated only upon the person's informed consent. If the person withholds consent, see subdivision (h) of this section.

- (iii) If a person is 18 years of age or older, but lacks the capacity to give informed consent regarding the proposed plan, or a determination of insufficient capacity has been made pursuant to paragraph (7) of this subdivision, informed consent shall be obtained from one of the surrogates listed, in the order stated:
 - (a) a guardian lawfully authorized to give such consent;
 - (b) an actively involved spouse;
 - (c) an actively involved parent;
 - (d) an actively involved adult child;
 - (e) an actively involved adult sibling;
 - (f) an actively involved adult family member;
 - (g) the Consumer Advisory Board (see section 633.99) for the Willowbrook Class (only for Class members it fully represents); or

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- (h) an informed consent committee (see paragraph (8) of this subdivision) or a court of competent jurisdiction.
 - (iv) If more than one party exists within a category on the list in subparagraph (i) or (iii) of this paragraph utilizing the standard of active involvement, consent shall be sought first from the party with a higher level of active involvement or, when the parties within a category are equally actively involved, consent shall be sought from any of such parties.
 - (v) If the first surrogate on the list in subparagraph (i) or (iii) of this paragraph is not reasonably available and willing, and is not expected to become reasonably available and willing to make a timely decision given the person's circumstances, application shall be made to the next surrogate on the list, in the order of priority stated.
 - (vi) Lack of informed consent, including the refusal or withdrawal of informed consent and objections are addressed in subdivision (h) of this section.
 - (vii) ICFs must also comply with 42 CFR 483.
- (7) Determination of capacity to give informed consent for persons who have not been judicially determined to be incapable of giving informed consent to restrictive/intrusive interventions.
- (i) In the first instance, it shall be the program planning team's responsibility to determine the person's capacity to give informed consent for each proposed restrictive/intrusive intervention. The team's determination and documentation shall be included in the person's record.
 - (ii) In those instances when a person's program planning team unanimously agrees that the person does not have the capacity to give informed consent to the proposed restrictive/intrusive interventions:
 - (a) The team shall prepare a written opinion and sufficiently detailed analysis of why it considers the person to be unable to provide informed consent. If the program planning team does not include a New York State licensed psychologist or New York State licensed physician, this opinion and analysis must be reviewed independently as outlined in (b).
 - (b) If the program planning team which determined a lack of capacity did not include a New York State licensed physician or New York State licensed

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psychologist, the opinion and analysis of the team shall be reviewed by a New York State licensed psychologist, or a New York State licensed physician (neither of whom is a member of the person's program planning team), who may or may not be an employee of the agency/facility. Such professional shall review the material provided and, in writing, document whether he/she agrees with the team's determination of the person's capacity to give informed consent. If the licensed professional disagrees with the team or cannot readily concur with the team's recommendation, the professional will examine the individual personally and document the findings of this examination in the person's record.

- (c) In the event that a development or reinstatement of a person's capacity for consent is unlikely, the person does not need to be re-evaluated annually, but the program planning team should review this opinion for currency annually. The assessment and capacity determination must be maintained in the person's current clinical record.
- (iii) If the program planning team is unable to unanimously agree or if the professional who conducted the personal examination disagrees with the team's decision regarding whether or not a person has the capacity to give informed consent, it shall be the responsibility of the agency's chief executive officer or designee to:
 - (a) Obtain from the person's program planning team, its written opinion and analysis of the person's ability to understand the proposed restrictive/intrusive intervention(s), and of the person's capacity to give or withhold informed consent;
 - (b) Obtain from a New York State licensed psychologist, or New York State licensed physician, either of whom has specialized training in developmental disabilities, a written opinion and analysis of the person's ability to understand each proposed restrictive/intrusive intervention, and of the person's capacity to give informed consent;
 - (1) The psychologist's or physician's written opinion shall be based upon a personal examination of the person.
 - (2) Said professional shall not be a member of the person's planning team and may or may not have an employment relationship with the agency/facility;
 - (c) Decide, after considering the opinions of the program planning team and the licensed psychologist or licensed physician, whether the person does or

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does not have the capacity to give informed consent, whether it is appropriate to obtain consent from a party or surrogate decision maker recognized by this section, and whether to proceed in accordance with the other provisions of this section; and

- (d) Ensure that the opinions of the program planning team, the licensed psychologist or physician, and the decision of the agency's chief executive officer or designee, are documented in the person's record and communicated to that person and to his or her actively involved adult family member or the Consumer Advisory Board, as appropriate, unless the person is an adult who has been determined to have the capacity to give informed consent and objects to such notice being made.
- (iv) Consent shall be considered to be in effect, once given (up to a maximum of one year), as long as the scope of the restrictive/intrusive intervention(s) remains within that proposed by the behavior support plan that was reviewed by the surrogate decision maker, and/or until such time as the need for the intervention has ceased, unless a lesser specific time limit has been stated at the time the consent was given. However:
 - (a) Any increase in the schedule of restrictive/intrusive intervention(s) beyond that originally presented, or the need for a different restrictive/intrusive intervention, requires a new consent from the person or appropriate surrogate; and
 - (b) If there is a change in the medical or psychological condition of the person receiving services which may affect the person's capacity to consent, the situation shall be reviewed immediately by the program planning team in consultation with the responsible clinician, and the outcome of this review will be documented. The continuing appropriateness of the proposed restrictive/intrusive intervention shall also be reviewed by the team.
- (v) Consent may be withdrawn by the consent giver *in writing* at any time, except that consent may be withdrawn by the person receiving services in the same manner as originally given (e.g., verbally, in writing) if he/she is the provider of consent. Documentation of the withdrawal of consent shall be included in a person's record. (Also see subdivision (h) of this section.)
- (8) Informed consent committee.
 - (i) This committee (see subdivision (b) of this section) need not be a "standing" committee. It may be a committee convened on an as-needed basis for the purpose

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of reviewing a request(s) for informed consent when the individual lacks capacity to give informed consent and there is no authorized surrogate reasonably available and willing.

- (ii) Agencies shall arrange for the creation of an informed consent committee or may coordinate with other agencies in the creation of a shared informed consent committee.
- (iii) Informed consent committee membership shall:
 - (a) consist of a minimum of three members;
 - (b) include at least one member having no ownership, employment relationship or other interest in the agency that would result in a real or perceived conflict of interest; or
 - (c) include at least one person who does not serve on the behavior plan/human rights committee which reviewed the behavior support plan; or
 - (d) include at least one professional holding a license or certification appropriate to their discipline, and who has specialized training or at least one year of professional experience in treating or working with people with developmental disabilities (see specific qualifications for each discipline under “professional, qualified” in section 690.99); and
 - (e) not include anyone who is involved in the delivery of services to the person whose service plan is under review; and
 - (f) include an individual with developmental disabilities, a guardian or family member of an individual with developmental disabilities, an advocate, or a party with experience in the field of developmental disabilities.
- (iv) The Mental Hygiene Legal Service (MHLS) may represent, before this committee, the interests of persons who are residents of a facility operated or certified by OPWDD, and shall be notified of any informed consent committee meetings involving such individuals who lack capacity.
- (v) The committee shall reach its decision within 15 business days of receiving an application for informed consent.
- (vi) The committee’s decision shall be by majority vote and shall be provided without delay to the person, the person’s program planning team and other relevant parties.

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(h) *Objections.*

- (1) Any objection to a person's proposed behavior support plan or a proposed revision of a current plan (except those relating to restrictive/intrusive interventions), must be made in accordance with the process that is outlined in section 633.12 of this Part.
- (2) Lack of informed consent.
 - (i) "Lack of informed consent" is considered to be:
 - (a) the withdrawal of a previously stated informed consent by the consent giver; or
 - (b) the refusal of the consent giver to provide informed consent.
 - (ii) The following applies to the use of restrictive/intrusive interventions except for the refusal of the person receiving services to take medication as described in paragraph (3) of this subdivision. If there is lack of informed consent, and the agency considers use of the intervention/treatment to be necessary to provide services safely and appropriately to the individual, the agency must apply for court approval for the use of such intervention/treatment. Notice of such application shall be sent to MHLS at the time of filing. While such a court application is pending, the agency may only use the restrictive/intrusive intervention in accordance with the emergency use provisions set forth in paragraphs (j)(1) and (j)(5). Agencies may also impose limitations on the person's rights in an emergency (see paragraph (j)(2)). However, if a surrogate consent giver has withdrawn consent for the administration of medication, and the immediate cessation of the administration of the refused medication would be harmful or dangerous to the person, then the medication shall be suspended in accordance with accepted medical practice. The surrogate shall be advised regarding the accepted medical practice for the suspension of the medication that is being followed by the agency.
- (3) Medication refusal. If an individual receiving services refuses to take medication to prevent, modify, or control challenging behavior or to treat a co-occurring diagnosed psychiatric condition, regardless of whether or not he or she is self-consenting (i.e. informed consent is provided by the individual receiving services), the administration of the refused medication must be suspended or not commenced.

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- (i) If the immediate cessation of the administration of the refused medication would be harmful or dangerous to the person, then the medication shall be suspended in accordance with accepted medical practice.
- (ii) Notification of an individual's refusal of medication shall be provided as soon as possible to the grantor of informed consent if the consent is given by a surrogate.
- (iii) Following the initial refusal of medication, the agency must continue to make attempts to provide the medication and to provide counseling to the individual regarding the need for the medication.
- (iv) If repeated attempts to resolve the issue of refusal of medication intended to modify or control challenging behavior or to treat a diagnosed psychiatric condition are unsuccessful, and the agency considers the administration of the medication to be necessary for effective treatment of the individual's condition, such agency must apply to a court of competent jurisdiction for a hearing to determine whether the individual has the capacity to make a reasoned decision with respect to the proposed medication use and whether the medication should be administered over objection. Notice of any such application shall be given to the authorized surrogate decision maker, if any, and the Mental Hygiene Legal Service.

(i) *Training.*

- (1) Staff, family care providers and respite substitute providers responsible for the support and supervision of a person who has a behavior support plan must be trained in the implementation of that person's plan.
- (2) Staff, family care providers and respite substitute providers responsible for the support and supervision of a person whose behavior support plan includes the use of a restrictive/intrusive intervention shall be trained in the particular intervention(s) to be utilized with a specific person, prior to use.
- (3) Staff who are responsible for implementing behavior support plans that incorporate the use of any physical intervention technique(s) must have:
 - (i) successfully completed an OPWDD-approved training course on the use of positive behavioral approaches, strategies and/or supports and physical intervention techniques; and
 - (ii) been certified or recertified in the use of positive behavioral approaches, strategies and/or supports and the use of physical intervention techniques by an Instructor, Instructor-Trainer or Master Trainer within the year. However, in the event that

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OPWDD approves a new curriculum, OPWDD may specify a period of time greater than one year before recertification is required.

- (4) Supervisors of such staff shall receive comparable training.
 - (5) If permitted by their graduate programs, graduate level interns may implement restrictive/intrusive interventions with appropriate supervision. The graduate level intern must also meet the requirements for training and certification specified in paragraphs (1) - (3) of this subdivision. Volunteers and undergraduate interns are not permitted to implement restrictive/intrusive interventions.
 - (6) Retraining of staff, family care providers and respite/substitute providers as described in paragraphs (1) and (2) of this subdivision shall occur as necessary when the behavior support plan is modified, or at least annually, whichever comes first.
 - (7) The agency must maintain documentation that staff, family care providers, respite/substitute providers, and supervisors have been trained and certified as required by this subdivision.
- (j) *Specific interventions.*
- (1) *Physical intervention techniques (includes protective, intermediate and restrictive physical intervention techniques).*
 - (i) The use of any physical intervention technique shall be in conformance with the following standards:
 - (a) The technique must be designed in accordance with principles of good body alignment, with concern for circulation and respiration, to avoid pressure on joints, and so that it is not likely to inflict pain or cause injury;
 - (b) The technique must be applied in a safe manner;
 - (c) The technique shall be applied with the minimal amount of force necessary to safely interrupt the challenging behavior;
 - (d) The technique used to address a particular situation shall be the least intrusive or restrictive intervention that is necessary to safely interrupt the challenging behavior in that situation; and
 - (e) All parties using the technique must have current certification or recertification in the use of positive behavioral approaches, strategies and/or

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supports and the use of physical intervention techniques by an Instructor, Instructor-Trainer, or Master Trainer.

- (ii) The agency shall provide adequate monitoring and oversight of all use of physical intervention techniques.
- (iii) Modification of existing techniques and new techniques.
 - (a) Modification of existing techniques.
 - (1) If any protective, intermediate or restrictive physical intervention technique needs to be modified (e.g., due to a particular person's physical disability), the modification shall be designed through consultation with an Instructor-Trainer and a health care professional.
 - (2) Notification of the modification of any physical intervention technique must be made in writing to a Master Trainer prior to use.
 - (3) Modification of intermediate and restrictive physical intervention techniques must be approved by the agency behavior plan/human rights committee prior to use.
 - (4) The modification of any physical intervention technique shall only be implemented with the person for whom it is designed.
 - (b) New techniques.
 - (1) If any *new* protective, intermediate or restrictive physical intervention technique needs to be developed (e.g., due to a particular person's physical disability, current or existing techniques are not effective), the new physical intervention technique shall be reviewed by a Master Trainer and a health care professional.
 - (2) The new technique must be approved by a Master Trainer prior to use.
 - (3) New intermediate and restrictive physical intervention techniques must be approved for use by the agency behavior plan/human rights committee prior to use.

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- (4) Any new physical intervention technique shall only be implemented with the person for whom it is designed.
- (iv) The use of any intermediate or restrictive physical intervention technique shall be terminated when it is judged that the person's behavior which necessitated application of the intervention has diminished sufficiently or has ceased, or immediately if the person appears physically at risk. In any event, the continuous duration for applying an intermediate or restrictive physical intervention technique for a single behavioral episode shall not exceed 20 minutes.
- (v) The use of any *restrictive* physical intervention technique must only be in response to a person engaging in behaviors that pose an immediate health or safety risk to the person or to others.
- (vi) After the use of any physical intervention technique (protective, intermediate, or restrictive), the person shall be inspected for possible injury as soon as reasonably possible after the intervention is used. The findings of the inspection shall be documented in the form and format specified by OPWDD or a substantially equivalent form. If an injury is suspected, medical care shall be provided or arranged. Any injury that meets the definition of a reportable incident or serious reportable incident must also be reported in accordance with Part 624.
- (vii) Each use of a *restrictive* physical intervention technique shall be reported electronically to OPWDD in the form and format specified by OPWDD.
- (viii) Whenever any intermediate or restrictive physical intervention technique has been used in an emergency, the service coordinator or party designated with the responsibility for coordinating a person's plan of services, and the appropriate clinician, if applicable, must be notified within two business days after the intervention technique has been used.
- (ix) Whenever any intermediate or restrictive physical intervention technique has been used in an emergency, the person's guardian, parent, actively involved family member, representative of the Consumer Advisory Board (for Willowbrook Class Members it fully represents), correspondent, or advocate must be notified within two business days after the intervention has been used, unless the person is a capable adult who objects to such notification.
- (x) The use of any intermediate or restrictive physical intervention technique in an emergency more *than two times in a 30-day period or four times in a six month period* shall require a comprehensive review by the person's program planning team, in consultation with a licensed psychologist, a licensed clinical social worker,

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or Behavioral Intervention Specialist. The team shall determine if there is a need for a behavior support plan to address the exhibited behavior(s), a need to change an existing plan, or to establish the criteria for determining if a plan will need to be developed in the future.

- (xi) The use of *restrictive* physical intervention techniques is not permitted in family care homes. The use of *restrictive* physical intervention techniques is not permitted in Hourly Community Habilitation unless specifically authorized by OPWDD.
 - (xii) The use of an intermediate or restrictive physical intervention technique that is not in conformance with the requirements of this section is considered to be physical abuse and must be reported pursuant to Part 624 of this Title (except as noted in subparagraph (xiii) of this paragraph).
 - (xiii) Notwithstanding any other provision of this section, any physical contact that is necessary to address an immediate health or safety risk to the person or to others, and which does not involve the use of more force than necessary, shall not be considered to be physical abuse pursuant to Part 624 or a violation of the requirements of this section. However, in the event that the level of physical contact would be considered to be comparable to an intermediate or restrictive physical intervention, the agency must comply with the provisions of subparagraphs (vii)–(ix) of this paragraph concerning visual inspection for possible injury and notifications. In addition, the person’s program planning team must be notified. The person’s program planning team shall consider whether changes might be needed in an existing behavior support plan or whether a plan needs to be developed.
- (2) *Rights limitations.*
- (i) The limitation of a person’s rights as specified in section 633.4 of this Part (including but not limited to: access to mail, telephone, visitation, personal property, electronic communication devices (e.g., cell phones, stationary or portable electronic communication or entertainment devices computers), program activities and/or equipment, items commonly used by members of a household, travel to/in the community, privacy, or personal allowance to manage challenging behavior) shall be in conformance with the following:
 - (a) limitations must be on an individual basis, for a specific period of time, and for clinical purposes only; and

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glossary). The use of a time-out room shall be in conformance with the following:

- (1) such action shall be taken only in accordance with a person's behavior support plan;
 - (2) constant auditory and visual contact shall be maintained. If at any time the person is engaging in behavior that poses a risk to his or her health or safety staff must intervene.
- (b) The use of a time-out room where normal egress is prevented, or placement of a person in a secured room or area from which he or she cannot leave at will, and which is not in conformance with the requirements of this section is considered, pursuant to Part 624, to be abuse.
- (c) The maximum duration of time a person can be placed in a time-out room shall not exceed *one continuous hour*. Use of a time-out room on *five or more occasions within a 24 hour period* shall require the review of the behavior support plan by the program planning team in consultation with the licensed psychologist, licensed clinical social worker, or Behavioral Intervention Specialist within three business days.
- (d) Each use of a time-out room in accordance with an individual's behavior support plan shall be reported electronically to OPWDD in the form and format specified by OPWDD.
- (e) Any time a room is to be used for time-out, that room must meet the following stipulations:
- (1) The room must be designated for time-out use by the chief executive officer and approved by the agency's governing body. Both the design and statement of intended use shall be approved by OPWDD.
 - (2) Time-out rooms are not permitted in family care homes.
 - (3) Environmental requirements are set forth as follows. Except as provided in subclause (4) of this clause, the room shall conform to the following requirements:
 - (i) Size: The minimum measurements of the room shall be 6' length x 8' wide x 8' height.

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- (ii) Decoration: Colors are selected to create a calm, relaxed atmosphere.
- (iii) Electrical:
 - (A) There shall be no electrical fixtures, outlets, switches, or wiring which may cause harm or injury to a person.
 - (B) There shall be no protruding light fixtures on any ceiling lower than 10' in height.
 - (C) There shall be no protruding light fixtures on any wall.
 - (D) Recessed light fixtures shall be designed to withstand tampering or destruction by the person in the room.
 - (E) Sprinkler heads, if provided, shall be the concealed type.
- (iv) Pipes: There shall be no exposed pipes. Coverings shall be designed to prevent the possibility of any pipes being grasped by the person.
- (v) Holes: There shall be no exposed holes.
- (vi) Protrusions: There shall be no protrusions on which a person might be injured. There shall be no protruding doorknob in the room. If the door is sufficiently padded to recess the knob, but still cause it to be accessible, this is permissible.
- (vii) Glass: The use of glass shall be minimized and unbreakable glass should be used whenever possible. Coverings for glass that is breakable are to be designed in such a way as to prevent being grasped by the occupant. Mirrors must be non-breakable.
- (viii) Padding: Padding or resilient wall covering shall be affixed to walls and the floor in such a fashion that it cannot be easily removed by the occupant. Provisions shall be made for the removal of the padding or wall covering for cleaning,

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repairing or altering of any such material (e.g., padding fastened securely to plywood panels which are then screwed to the walls), unless the wall surface cover is such that it can be cleaned, maintained, and repaired in place. In facilities where the interior finish rating is required (i.e. Life Safety Code compliant facilities) the finish rating of the wall or floor surfaces shall be equal to or greater than that required by the Life Safety Code.

- (ix) Occupant comfort:
 - (A) There shall be adequate measurement equipment to ensure control of temperature, humidity and circulation of air within the room.
 - (B) The floor surface covering shall be consistent with the needs of the person using the room.

- (x) Soundproofing: If soundproofing of the time-out room is necessary for the comfort of other people receiving services, it shall be determined if there will be sufficient transmittal of sound (e.g., adequate to hear words spoken by the person within the room) through the observation window or whether other means of maintaining auditory contact are necessary.

- (xi) Furnishings: There shall be no furniture or other objects in the room.

- (xii) Observation:
 - (A) Observation windows shall not be covered by mesh, bars, or wire material.
 - (B) An opening containing only mesh, bars, or wire material shall be unacceptable as an “observation window.”
 - (C) The viewing area shall be sufficiently large to maximize visual observation. The person shall be in at least partial view at all times (i.e., there must be no blind areas large enough for the person to be completely out of sight). This shall not be construed to mean that the design of the room must provide for

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the capability of observing every action, facial expression, etc., should the person be standing/sitting in such a position or location that limits the view.

- (D) The viewing area shall be designed to be functional, taking into account the comfort and suitability for use by staff.
 - (xiii) Windows (other than observation windows) shall be completely covered with a false wall to ensure the person's safety and to eliminate distraction and/or visual stimulation in what is intended to be a non-stimulating environment.
 - (xiv) Doors shall swing outward from the inside. Doors may be locked only by the continuous physical action of staff. The door release mechanism must be designed in such a way that if staff are not applying pressure, or physically holding the release mechanism, the door lock automatically releases.
 - (xv) Door thresholds shall not protrude creating a trip hazard. These shall be flush with the floor or ramped.
 - (xvi) There shall be a clock visible to staff to monitor the duration of the time-out.
 - (xvii) The room must be cleaned and disinfected regularly and after each use.
- (4) Exceptions to specific physical plant requirements in subclause (3) of this clause.
- (i) OPWDD may waive specific physical plant requirements upon the application of an agency.
 - (ii) Time-out rooms which were in existence on the effective date of this section are not required to comply with the specific physical plant requirements if the time-out room was approved by OPWDD prior to the effective date. A new OPWDD waiver is not required in this situation. However, OPWDD approval is required for any significant modification of such time-out room which occurs on or after the effective date.

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- (5) If a time-out room must be secured when not in use, the mechanism used for this purpose shall be such that the door can be opened, at will, from the inside.
- (4) *Mechanical Restraining Devices.*
- (i) *General provisions.*
 - (a) Mechanical restraining devices shall be employed:
 - (1) in accordance with the principles of correct body alignment;
 - (2) in a manner that does not interfere with circulation and respiration; and
 - (3) with concern for a person's comfort.
 - (b) Mechanical restraining devices shall only be used in a manner consistent with the provisions of this section. Any other use shall be reported as abuse in conformance with Part 624.
 - (c) The use of mechanical restraining devices in an emergency is not permitted.
 - (d) Mechanical restraining devices *used as a support* to achieve proper body position, balance, or alignment, as part of a medical or dental procedure or as a medical or dental safeguard are not subject to the requirements of this section.
 - (e) Mechanical restraining devices shall be maintained in a clean and sanitary condition, and in good repair.
 - (f) Agency policies/procedures governing the use of mechanical restraining devices shall address the sanitizing and storage of, and methods of limiting access to, the devices.
 - (g) Helmets with any type of chin strap shall not be used while a person is in the prone position, reclining, or while sleeping, unless specifically approved by OPWDD.
 - (h) Barred enclosures and the use of bed linen employed to restrain movement shall be prohibited under all circumstances.

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- (i) Nothing in this section shall preclude the use of a mechanical restraining device(s) while a person is an inpatient or resident under the auspices of a non-OPWDD operated or certified facility, program or service (e.g., mental health provider, medical hospital, or jail). The use of a mechanical restraining device in these types of settings is not subject to the provisions of this section and is subject instead to the applicable policies and rules of that provider. The use of mechanical restraining devices in such settings is not subject to the requirements of this section or Part 624.
 - (j) The use of devices to limit movement for the safe transport of the individual in vehicles, wheelchairs, etc., is not considered to be the use of a mechanical restraining device, and is not subject to the requirements of this section.
- (ii) *Planned use of mechanical restraining devices.*
- (a) Mechanical restraining devices to prevent or modify challenging behavior may only be used in accordance with a behavior support plan if the devices meet the following criteria:
 - (1) the device shall be designed and used in such a way as to minimize physical discomfort and to avoid physical injury;
 - (2) the device shall be commercially available and designed for human use. Alternatively, if the device is not commercially available or is not designed for human use (e.g., modification of a commercially available device), it must be approved by the behavior plan/human rights committee and approved by OPWDD; and
 - (3) an occupational or physical therapist has been consulted if modification of the device is needed.
 - (b) The following types of devices (in the specified circumstances) may be used without specific OPWDD approval:
 - (1) mittens, helmets, face masks, goggles, sleeve boards (by whatever name known), clothing (e.g., jumpsuit, leotard, or custom-designed clothing such as shirts or pants made of non-shredable cloth), bolsters, and mats used to safely contain a person;

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- (2) lap trays, seatbelts, and harnesses; only when used to maintain an ambulatory person in a fixed location for the purpose of enhancing services; and
 - (3) the use of a seatbelt, harness, or mechanical brake to maintain a non-ambulatory person in a fixed location for the purpose of preventing risk to health or safety resulting from challenging behavior.
- (c) The use of devices other than as specified in clause (b) of this subparagraph is permitted only if specifically approved by OPWDD.
- (d) Application to obtain the approval of OPWDD to use a specific mechanical restraining device shall be submitted by the chief executive officer and shall include such information as may be required by OPWDD.
- (e) The behavior support plan, consistent with the physician's order (see clause (g) of this subparagraph) shall specify the following conditions for the use of a mechanical restraining device:
- (1) the facts justifying the use of the device;
 - (2) staff or family care provider action required when the device is used;
 - (3) criteria for application and removal and the maximum time period for which it may be continuously employed, see clause (i) of this subparagraph;
 - (4) the maximum period of time for monitoring the person's needs, comfort, and safety, see clause (j) of this subparagraph; and
 - (5) a description of how the use of the device is expected to be reduced and eventually eliminated.
- (f) A behavior support plan may include the use of mechanical restraining devices to enable a person to participate safely and effectively in habilitative programming, recreation, social, and/or other activities. The plan shall be designed to reduce the frequency/severity of the challenging behavior so that non-restrictive/non-intrusive means of managing and eliminating challenging behavior(s) can be implemented.

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- (g) A physician's order is required for the use of a mechanical restraining device as part of a behavior support plan. The order shall be renewed as specified in the plan, but in all cases no less frequently than every six months. The order shall:
 - (1) specify the type of device to be used;
 - (2) set forth date of expiration of the order;
 - (3) specify any special considerations related to the use of the device based on the person's medical condition, including whether the monitoring which is required during and after use of the device must incorporate specific components such as checking of vital signs and circulation; and
 - (4) be retained in a person's clinical record with a full record of the use of the device.

- (h) Notwithstanding any other provision of this section, if the device is used solely to maintain an ambulatory person in a fixed location or position for the purpose of enhancing the delivery of services a physician's order is not required. This use must conform to all other requirements of this paragraph, including the requirements for release specified in clause (i) of this subparagraph.

- (i) Release from the device:
 - (1) Except when asleep a person in a mechanical restraining device shall be released from the device *at least once every hour and fifty minutes for a period not less than ten minutes*, and provided the opportunity for movement, exercise, necessary eating, drinking and toileting.
 - (2) If the person requests release for movement or access to a toilet before the specified time period has elapsed, this should be afforded to him/her as soon as possible.
 - (3) If the person has fallen asleep while wearing a mechanical device, opportunity for movement, exercise, necessary eating, drinking and toileting shall always be provided immediately upon waking if more than one hour and fifty minutes has elapsed since the device was employed or the end of the last release period.

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- (4) If a physician specifies a shorter period of time for release, the person shall be released in accordance with the physician's order.

- (j) *At least once every 30 minutes*, including when a person is asleep, or more frequently if directed by a physician or previously designated in a risk management or behavior support plan, the person's physical needs, comfort, and safety shall be monitored. Monitoring shall incorporate any specific components that are included in the physician's order (e.g. checking vital signs and circulation). If the person is asleep, this monitoring shall be completed through observation only while not awakening the person. The person shall also be monitored after removal of the mechanical restraining device. Documentation of the monitoring and action taken must be entered in the person's clinical record.

- (k) If, upon being released from a mechanical restraining device before the time limit specified in the order, a person makes no overt gesture(s) that would threaten serious harm or injury to self or others, the mechanical restraining device shall not be reemployed by staff unless the behavior which necessitated the use of the device reoccurs.

- (l) The planned use of a device which will prevent the free movement of both arms or both legs, or totally immobilize the person, may only be initiated by a written order from a physician after the physician's personal examination of the person. The physician must review the order and determine if it is still appropriate each time he or she examines the person, but at least every 90 days. The review must be documented. The planned use of stabilizing or immobilizing holds or devices during medical or dental examinations, procedures, or care routines must be documented in a separate plan/order and must be reviewed by the program planning team on at least an annual basis.

- (m) A device which will prevent the free movement of both arms or both legs or totally immobilize the person may only be applied under the supervision of a senior member of the staff or, in the context of a medical or dental examination or procedure, under the supervision of the healthcare provider or staff designated by the healthcare provider . Staff assigned to monitor a person while in a mechanical restraining device that totally immobilizes the person shall stay in continuous visual and auditory range for the duration of the use of the device.

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- (5) *Medication.*
- (i) *General provisions.*
- (a) All use of medication must be in conformance with Part 624 of this Title and sections 633.4, 633.10, and 633.17 of this Part.
- (b) The use of medication to modify or control challenging behavior or to treat symptoms of a diagnosed co-occurring psychiatric disorder shall not:
- (1) replace the need to develop an appropriate program plan;
- (2) be intentionally administered in amounts that interfere with a person's ability to participate in programming or other activities;
- (3) be used for disciplinary purposes; or
- (4) be used for the convenience of staff or as a substitute for supervision.
- (c) The use of medication to modify or control challenging behavior not in conformance with this paragraph shall constitute abuse and must be reported in conformance with Part 624. The use of medication prescribed or administered to individuals in conjunction with, or to facilitate or relieve distress related to medical or dental examinations or procedures is not subject to the requirements of this section.
- (d) A semi-annual medication regimen review that includes any medications prescribed to treat a co-occurring diagnosed psychiatric disorder, or to prevent, control, modify or eliminate challenging behavior(s), must be conducted in accordance with section 633.17 of this Part. The results of these medication regimen reviews shall be shared with the person's program planning team and the prescriber, and documented in the person's record, in order to assist healthcare providers and the team to evaluate whether the benefits of continuing the medication(s) outweigh the risk inherent in potential side effects.
- (e) At least semi-annually, and more frequently as needed, staff shall consult with the prescriber regarding the administration and continued effectiveness of the medication.

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- (f) It shall be the responsibility of the agency to ensure that the person or the party granting informed consent has been given clear, necessary information regarding the proposed medication including, but not limited to, its purpose, and the dose or dosage range and route of administration. (See subparagraph (b)(12)(ii) of this section for the basic elements of the information necessary for informed consent.)
- (g) Lack of informed consent for, or the refusal of, medication intended to modify or control challenging behavior or medication use to treat a co-occurring diagnosed psychiatric condition is addressed in subdivision (h) of this section.
- (ii) *Planned/routine use of medication.*
 - (a) Medication to prevent, control, or modify challenging behavior, or to prevent or reduce symptoms of a diagnosed co-occurring psychiatric condition, must be administered only as an integral part of a behavior support plan or monitoring plan, in conjunction with other interventions which are specifically directed toward the potential reduction and eventual elimination of the challenging behavior(s) or target symptoms of the diagnosed co-occurring psychiatric condition.
 - (b) Written informed consent shall be obtained prior to the use of the medication. If it is necessary for the medication to be administered before written informed consent can reasonably be obtained, verbal consent may be accepted for only the period of time before written informed consent can be obtained. Verbal consent must be witnessed by two members of the staff and documented in the person's record. This verbal consent may be considered valid for a period of up to 45 days.
 - (c) The use of medication shall have a documented positive effect on the person's behavior or target symptoms to justify its ongoing use.
 - (d) The effectiveness of the medication shall be re-evaluated at least semi-annually at the program plan reviews by the program planning team in consultation with a licensed psychologist, licensed clinical social worker, or Behavior Intervention Specialist, and a health care professional. The goal(s) of this aspect of the plan review include: ensuring that medication is at the minimum and most effective dose; identifying a potential need for a medication with fewer or less intrusive side effects; evaluating the evidence presented to support continuation of the medication at a maintenance level,

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or recommending reduction or discontinuation of medication use if clinically indicated and authorized by the prescriber.

- (e) Additional requirements concerning the use of medication to treat a co-occurring diagnosed psychiatric condition are found in subparagraph (vi) of this paragraph.
- (iii) *Planned use of as-needed orders for medication.*
- (a) “As-needed” (also known as “PRN”) orders for medication to prevent, modify, or control challenging behavior, or to reduce symptoms of a diagnosed co-occurring psychiatric condition, are considered planned use and must be incorporated in and documented as part of a behavior support plan or a monitoring plan.
 - (b) The person shall have a recent documented history of displaying the behavior(s) or symptoms (occurring in the last 12 months) for which the as-needed medication is being prescribed.
 - (c) The behavior support plan or monitoring plan, consistent with the prescriber’s order, shall clearly state:
 - (1) the conditions under which the “as-needed” medication is to be administered, including the nature and degree of the individual’s symptoms, and the prescriber’s recommendations regarding proximity to any scheduled medication administration;
 - (2) the expected therapeutic effects; and
 - (3) if applicable, the conditions under which the medication can be re-administered, and the allowable frequency of re-administration.
 - (d) The staff person or family care provider who is responsible for support and supervision of a person who has a behavior support plan or monitoring plan must document in the person’s clinical record a summary of the results of the medication use in behavioral terms.
 - (e) Results that are substantively different from the intended effect, and any adverse side effects, shall be reported to the prescriber immediately and the person’s program planning team no later than the next business day.

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- (f) If any as-needed medication is administered on *more than four (4) separate days (one day equals 24 hours) in a 14-day period*, the individual's program planning team, in consultation with the licensed psychologist, licensed clinical social worker, or Behavioral Intervention Specialist and healthcare professional, must reassess the appropriateness of continuing the as-needed medication, or consider recommending that it be incorporated into the individual's regular drug regimen.
 - (g) Each use of an as-needed medication to prevent, modify, or control challenging behavior shall be reported electronically to OPWDD in the form and format specified by OPWDD.
 - (h) If the as-needed medication is not administered during a 6-month period, the program planning team, in consultation with the licensed psychologist, licensed clinical social worker, or Behavioral Intervention Specialist, must review the behavior support plan and develop a recommendation to the prescriber regarding the appropriateness of continuing the as-needed medication as part of the plan. If the order is continued, a clear justification is to be documented in the record.
- (iv) *Emergency use of medication.*
- (a) Medication may be administered in an emergency, without informed consent, with the express intent of controlling a person's challenging behavior or acute symptoms of a diagnosed co-occurring psychiatric condition when:
 - (1) the person's behavior constitutes an immediate risk to the health or safety of the person or others; or
 - (2) in a physician's judgment, an emergency exists that creates an immediate need for the administration of such medication, and an attempt to secure informed consent would result in a delay which would increase the risk to the health or safety of the person or others.
 - (b) The administration of such medication may only continue for as long as one of the conditions in clause (a) of this subparagraph exists.
 - (c) The use of the medication, along with the prescription/order and a note on its effectiveness, shall be documented in the person's record.

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- (d) The emergency use of medication to manage challenging behavior or acute symptoms of a diagnosed co-occurring psychiatric condition in *more than four (4) instances in a 14-day period* shall require a comprehensive review by the program planning team in consultation with the licensed psychologist, a licensed clinical social worker or Behavioral Intervention Specialist within three business days of the fifth medication administration;
 - (1) The team shall determine if there is a need for a behavior support plan to address the behavior or symptom that necessitated the emergency use of medication, or a need to modify an existing plan, or to establish the criteria for a future decision that a plan will be needed. Such a determination shall be documented.
 - (2) The emergency administration of the medication may continue until the program planning team meets.
- (e) Whenever it is or has been necessary to utilize any medication to control challenging behavior or acute symptoms of a diagnosed co-occurring psychiatric condition in an emergency, the duly authorized surrogate consent giver in accordance with paragraph (g)(6) of this section, the service coordinator or party designated as responsible for coordinating a person's plan of services, and the appropriate clinician (e.g., licensed psychologist, licensed clinical social worker, Behavioral Intervention Specialist, physician), if applicable, shall be notified within the next two business days.
- (f) Each use of an emergency medication solely to control challenging behavior shall be reported electronically to OPWDD in the form and format specified by OPWDD.
- (v) *Short-term use of medication -- when there is no behavior support plan.*
 - (a) This subparagraph does not apply to ICFs. (ICFs must comply with 42 CFR 483.)
 - (b) In the absence of a behavior support plan which incorporates the use of a specific medication, medication to modify or control challenging behavior may be administered on a short-term basis when all of the following conditions are met:

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- (1) an untoward or unanticipated condition, reaction, symptom, event or situation has occurred which creates exceptional circumstances that, if left untreated could potentially lead to an emergency situation;
 - (2) the circumstances resulting from the event are expected to last for a time period longer than that which can be considered an emergency;
 - (3) the medication is deemed to be the most effective course of treatment; and
 - (4) the medication is ordered by a prescriber.
- (c) Informed consent is required prior to the administration of the medication. If it is necessary for the medication to be administered before written informed consent can be reasonably obtained, *verbal consent* may be accepted for only the period of time before written informed consent can be reasonably obtained, but no longer than 45 days. Verbal consent must be witnessed by two members of the staff and documented in the person's record.
- (d) Within five working days of the first administration of the medication or of the admission to such programs of a person with such a pre-existing medication regimen, a person's program planning team, in consultation with a licensed psychologist, licensed clinical social worker, or Behavioral Intervention Specialist, shall conduct a review of the circumstances which necessitated the use of such medication. The program planning team shall determine if it is necessary to develop a behavior support plan to modify or control the behavior or to modify an existing plan of services, or shall establish the criteria for a future decision that a plan will be needed. All determinations shall be documented.
- (e) Without incorporation into a behavior support plan and written informed consent, the administration of the medication shall not continue for *more than 30 consecutive days and no more than 45 days in a calendar year*.
- (vi) *Medication use to treat a co-occurring diagnosed psychiatric condition.*
- (a) Medication may be used as part of the treatment for the symptoms of a co-occurring diagnosed psychiatric condition, including challenging behavior that occurs exclusively or almost exclusively as a result of that condition. The following requirements must be met.

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- (1) In order to be considered “medication to treat a co-occurring diagnosed psychiatric condition,” the medication must be prescribed for the treatment of a specific psychiatric condition, in a manner consistent with generally accepted psychiatric practice.
- (2) The term “psychiatric condition” means those psychiatric conditions which are recognized as such by the American Psychiatric Association or World Health Organization. For the purposes of this section, the term “co-occurring psychiatric condition” does not refer to the following: mental retardation, learning disorders, motor skills disorders, communication disorders, pervasive developmental disorders, attention-deficit and disruptive behavior disorders, and impulse control disorders.
- (3) The use of the medication must be in conformance with the applicable requirements of subparagraph (j)(5)(i).
- (4) The use of the medication shall be consistent with accepted standards of clinical practice, including treatment of the symptoms of the diagnosed psychiatric condition.
- (5) The symptoms and diagnosis of the co-occurring psychiatric condition must be documented.
- (6) Target symptoms for the psychiatric condition shall be identified and documented in practical, operationally defined terms to permit reliable, ongoing data collection and assessment of treatment effectiveness.
- (7) The use of medication and the target symptoms shall be specified and documented in a written monitoring plan. The plan should specify how progress reflected in symptom reduction and relevant functional improvement, or lack of progress, will be measured and documented. If all of the requirements of this clause are met, the agency is not required to conduct and document a functional behavioral assessment or develop a behavior support plan, as long as other behavioral interventions are not needed for the individual to address challenging behaviors which do not reflect the psychiatric symptomatology. The monitoring plan shall describe how challenging behavior(s) -- including those that reflect psychiatric symptomatology, should they occur -- will be addressed through the use of other appropriate interventions. If it is expected that the

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person might need restrictive/intrusive interventions, a functional behavioral assessment and behavior support plan must be developed.

(8) Informed consent must be obtained for the use of the medication.

- **Paragraph 81.5(b)(5) is deleted and paragraph (6) is renumbered as paragraph (5).**

[(5) The governing body shall appoint a special review committee, including members of the professional clinical staff which shall:]

[(i) Develop a written special review plan subject to approval by the governing body and the department. This plan shall provide for review of all untoward incidents which may occur and extra risk procedures administered. Untoward incidents may include, but not be limited to, serious drug reactions, suicides and sudden death, assaults, accidents, unauthorized absences and terminations of service against professional advice. Extra risk procedures may include, but not be limited to behavior modification, somatic therapies, experimental treatment modalities, and restraint or seclusion.]

[(ii) Review and evaluate untoward incidents and extra risk procedures in accordance with the plan.]

[(iii) Determine the facts in any incident reviewed, review ongoing practices and procedures in relation to such incidents and extra risk procedures, and recommend changes in policies, practices or procedures which may be indicated.]

[(iv) Include either on a regular membership basis or by special arrangement as indicated the participation of appropriately qualified and experienced physicians.]

[(v) Meet as often as necessary to properly execute its functions and in no event less often than quarterly, keeping written minutes of its deliberations and submitting reports to the governing body as necessary.]

- **Paragraph 624.4(b)(4) is deleted and the rest of the subdivision is renumbered.**

[(4) Restraint. The act of limiting or controlling a person's behavior through the use of:
(i) Any device which prevents the free movement of both arms or both legs, as ordered by a physician.
(ii) Any device which totally immobilizes (see glossary) a person, as ordered by a

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physician.

(iii) Any device which is ordered for the express purpose of controlling behavior in an emergency (see glossary)

NOTE: Nothing in this Part shall prevent the use of mechanical supports to provide stability necessary for therapeutic measures such as immobilization of fractures, administration of intravenous or other medically necessary procedures.

(iv) Any medication as ordered by a physician which renders a person unable to satisfactorily participate in programming, leisure or other activities.]

- **Paragraph 624.4(c)(1) is amended as follows:**

(1) Physical abuse. Prior to the date specified in paragraph 633.16(a)(6) of this Title, physical abuse means physical [Physical] contact which may include, but is not limited to such obvious physical actions as hitting, slapping, pinching, kicking, hurling, strangling, shoving, unauthorized or unnecessary use of personal intervention, or otherwise mishandling a person receiving services. Physical contact which is not necessary for the safety of the person and/or causes discomfort to the person may also be considered to be physical abuse, as may the handling of a person with more force than is reasonably necessary. On or after the date specified in paragraph 633.16(a)(6) of this Title, physical abuse means non [Non]-accidental physical contact that may include such physical actions as hitting, slapping, pinching, kicking, hurling, strangling, shoving, dragging, or otherwise handling a person with more force than is reasonably necessary. The use of any intermediate or restrictive physical intervention (see glossary, section 624.20) technique in a manner which is not in conformance with the requirements of section 633.16 of this Title is also considered to be physical abuse for facilities and services which are required to comply with that section. For all other programs or services, any use of an intermediate or restrictive physical intervention technique is considered to be physical abuse unless it is specifically authorized by OPWDD. However, any physical contact that is necessary to address an immediate health or safety risk to the person or to others shall not be considered to be physical abuse.

- **Paragraphs 624.4(c)(4)-(7) are amended as follows:**

(4) Seclusion. The placement of a person in a secured room or area from which he or she cannot leave at will. Prior to the date specified in paragraph 633.16(a)(6) of this Title, this [This] does not include placement in a time-out (see glossary, section 624.20) room as part of a behavior [management] support plan that meets all applicable requirements. On or after the date specified in paragraph 633.16(a)(6) of this Title, this does not include placement in a time-out (see glossary,

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section 624.20) room in accordance with section 633.16 of this Title. Seclusion is considered to be a form of abuse and is, therefore, prohibited.

(5) Restraint.

(i) The following definition is effective prior to the date specified in paragraph 633.16(a)(6) of this Title: Unauthorized or inappropriate use of restraint. The use of a mechanical restraining device to control a person without the written, prior authorization of a physician or the senior staff member (see glossary) if the physician cannot be present within 30 minutes; or the use of a mechanical restraining device without it being specified in a plan of services; or used for medical purposes (see glossary) without a physician's order. The intentional use of a medication to control a person's behavior that has not been prescribed by a physician for that purpose is considered to be unauthorized use of restraint. Inappropriate use of a restraint shall include, but not be limited to, the use of a device(s) or medication for convenience, as a substitute for programming, or for disciplinary (punishment) purposes.

(ii) The following definition is effective on or after the date specified in paragraph 633.16(a)(6) of this Title: Unauthorized use of restraint. The use of a mechanical restraining device which is not in conformance with the requirements of section 633.16 of this Title, for facilities or services which are required to comply with that section. "The unauthorized use of restraint" also includes the intentional use of medication to control a person which is not in conformance with the requirements of section 633.16 of this Title, for residential facilities certified or operated by OPWDD. For other programs and services, any use of a mechanical restraining device is also considered to be unauthorized use of restraint unless such use is: specifically authorized by OPWDD, prescribed for the person, and in accordance with the prescriber's instructions. In addition, for programs and services other than residential facilities certified or operated by OPWDD, the use of medication to modify or control behavior is considered to be unauthorized use of restraint unless the medication is prescribed for a person and is administered in accordance with the prescriber's instructions.

(6) The [unauthorized or inappropriate] use of aversive conditioning (see conditioning, aversive in glossary, section 624.20). [The use of aversive conditioning without appropriate permissions is the unauthorized use of aversive conditioning. Inappropriate use of aversive conditioning shall include, but not be limited to, the use of the technique for convenience, as a substitute for programming, or for disciplinary (punishment) purposes.]

(7) Time-out.

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- (i) The following definition is effective on or after the date specified in paragraph 633.16(a)(6) of this Title: The unauthorized or inappropriate use of time-out (see "time-out" in glossary). The use of time-out without appropriate permissions is the unauthorized use of time-out. Inappropriate use of time-out shall include, but not be limited to, the use of the technique for convenience, as a substitute for programming, or for disciplinary (punishment) purposes.
 - (ii) The following definition is effective on or after the date specified in paragraph 633.16(a)(6) of this Title: The unauthorized use of time-out (see "time-out" in glossary, section 624.20). The use of time-out which is not in conformance with the requirements of section 633.16 of this Title for facilities and services which are required to comply with that section. In addition, for other programs and services, any use of time-out is considered to be unauthorized use of time-out unless specifically authorized by OPWDD.
- **Section 624.20 is amended by the amendment of subdivision (o), the deletion of current subdivisions (x) and (aa), the addition of a new subdivision (aa), the deletion of subdivisions (ae), (ak), and (ao) and the amendment of current subdivision (aq). The subdivisions in Section 624.20 are kept in alphabetical order by relettering as needed.**
- (o) Conditioning, aversive. [Contingent upon a person's behavior, the application to a person's body of a physical stimulus to modify or change behavior with such stimulus being reasonably considered extremely uncomfortable or painful, or which may be noxious to the person. Examples of such stimuli include, but are not limited to: water and other mists or sprays, noxious odors (e.g., ammonia), noxious tastes (e.g., Tabasco), corporal punishment (e.g., slapping, spanking, hitting, or pinching), air blasts, blindfolds, white noise helmets, and electric shock.] The contingent application of a physical stimulus or device to a person's body or senses in order to modify or change behavior. Such a stimulus or device must be reasonably considered to be significantly uncomfortable, painful, or noxious to the person when applied. Examples of such stimuli may include, but are not limited to: water and other mists or sprays, noxious odors (e.g., ammonia), noxious tastes (e.g., hot sauce), corporal punishment (e.g., slapping, spanking, hitting, or pinching), air blasts, blindfolds, white noise helmets, and electric skin shock.
 - [(x) *Emergency*. As used in this Part, a situation that is unexpected, unforeseen, or unanticipated and thus, no provision has been made in a person's plan of services through the development of a behavior management plan to address how it is to be handled by staff.]
 - [(aa) *Immobilizes, totally*. The use of a restraining sheet or the complete curbing of the movement of the arms, legs, or torso through the use of (but not limited to):
 - (1) securing of arms and legs directly to another object (e.g., straps or shackles on a chair);
 - (2) four point restraint; or

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(3) a bed sheet, towel, or similar item wrapped around a person.]

(aa) Intervention, physical. Those intervention techniques, or the adaptations of such, that include hands-on techniques that deflect, protect from, or release hits, kicks or grabs by persons receiving services toward others in their environment, or holds of limited duration that may reduce, limit, or restrict an individual's freedom of movement in order to interrupt or control challenging behavior that is posing an immediate health or safety risk to the person or to others. There are three categories of physical intervention techniques:

(1) protective techniques, which include blocks, deflection strategies and grab releases;

(2) intermediate techniques, which include holds and escorts intended to maintain a person in a standing or seated position to reduce or limit movement, to maintain health and safety, and/or to remove a person from an unsafe location or situation;

(3) restrictive techniques, which include holds that restrict freedom of movement in order to interrupt or control behavior that is posing an immediate health or safety risk, and involve taking a person from a standing position to the floor or holding the person on the floor.

[(ae) *Member, senior staff.* As used in this Part, that staff member, by whatever title he or she may be known, who is designated as a senior member of the administrative structure of an agency, and, as such, may carry out designated responsibilities delegated to the chief executive officer. This may be someone who is responsible for a group of facilities (e.g., program administrator), or who is immediately in charge of a facility or of a designated area (e.g., residence manager, head of shift, unit supervisor). In conformance with the Mental Hygiene Law, section 33.04, such senior staff members may also be designated by the chief executive officer as having the authority to impose a mechanical restraining device in an emergency, when appropriately trained in their use and application.]

[(ak) *Purposes, (device for) medical.* A mechanical restraining device which controls movement and which is prescribed by a physician or dentist to facilitate a specific medically necessary procedure; or for time-limited periods for explicit medical reasons during healing. Examples of devices used during healing would include a brace to keep a limb in place, splints or braces to provide stability for broken bones, devices to prevent or avoid irritation or further injury of a skin ailment or burn, and traction equipment.]

[(ao) *Supports.* Those mechanical restraining devices, ordered on at least an annual basis by a physician in consultation with a person's program planning team, needed to assist the person in his or her comfort, functioning, and/or safety. Supports approved by OPWDD are:

(1) devices which maintain a person's body in good alignment;

(2) devices which maintain a person in a safe and/or appropriate position when a person is not capable of self-support or self-ambulation; and

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- (3) devices (such as helmets) which protect the head of a person with a health problem (e.g., seizures) that necessitates such a safeguard.]
- (aq) *Time-out.* Prior to the date specified in paragraph 633.16(a)(6) of this Title, a [A] behavioral [management] intervention in which a person is temporarily removed from or denied the opportunity to obtain reinforcement and during which the person is under visual or auditory contact and supervision. When a room is used for time-out purposes, normal egress from that room can only be prevented by the direct physical action of appropriately trained staff and when such action is designated in a written plan. The placement of a person in a secured room or area from which he or she cannot leave at will, for other than the purpose of time-out, is prohibited and is considered to be a form of abuse. Time-out is not considered to be a form of aversive conditioning (see glossary).

On or after the date specified in paragraph 633.16(a)(6) of this Title, time-out is a restrictive/intrusive intervention in which a person is temporarily removed from reinforcement or denied the opportunity to obtain reinforcement and during which the person is under constant visual and auditory contact and supervision. Time-out interventions include:

- (1) placing a person in a specific time-out room, commonly referred to as exclusionary time-out;
- (2) removing the positively reinforcing environment from the individual, commonly referred to as non-exclusionary time-out.
- **Paragraph 633.4(a)(7) is amended as follows:**

(7) None of the foregoing rights shall be limited [for disciplinary (punishment) purposes, retribution or for the convenience of staff] for the convenience of staff, as a threat, as a means of retribution, for disciplinary purposes or as a substitute for treatment or supervision.
 - **Paragraph 633.17(a)(18) is amended by the addition of a new subparagraph (iii) as follows:**

(iii) To the extent that requirements of paragraph 633.16(j)(5) of this Part are more rigorous than the requirements of this paragraph (18), the requirements of paragraph 633.16(j)(5) are controlling.
 - **Section 633.99 is amended by the amendment of subdivisions (m), (p), and (z), the addition of a new subdivisions (ax) and (ci), and the amendment of subdivision (cs) as follows. The subdivisions in Section 633.99 are kept in alphabetical order by relettering as needed.**

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- (m) *Available, reasonably.* A surrogate to be contacted can be contacted with diligent efforts within a reasonable time by an attending physician or other party seeking to obtain either informed consent for the purposes of sections 633.11 or 633.16 of this Part, or a DNR decision pursuant to section 633.18 of this Part.
- (p) *Capacity.* The ability to adequately understand and appreciate the nature and consequences of professional medical treatment (see glossary), behavior support plans, pursuant to section 633.16 of this Part and DNR orders (see glossary), including the benefits and significant risks and alternatives to such treatment/plans so as to be capable of making a decision thereto in a knowing and voluntary manner. A person's decision relative to the proposed professional medical treatment, proposed plan or proposed DNR order shall not, in and of itself, be the exclusive basis for the determination of capacity.
- (z) *Consent, informed.*
- (1) For the purposes of this Part, *informed consent* shall mean the effective knowing consent by a person (or his/her legally authorized surrogate) with sufficient capacity to consent and so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. Such consent shall be in writing, except in the case of:
- (i) consent for research involving more than minimal risk where there is a waiver of consent; or
 - (ii) a waiver of the need for written consent as allowed in 45 CFR 46.117(c) to ensure confidentiality[.]; or
 - (iii) the use of short term medication pursuant to subparagraph 633.16(j)(5)(v) (with limitations); or
 - (iv) the use of restrictive/intrusive interventions or rights limitations pursuant to paragraph 633.16(g)(1) (with limitations).
- (2) The basic elements of information necessary to such informed consent include:
- (i) a fair explanation to the person or surrogate of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
 - (ii) a description of any attendant discomforts and risks reasonably to be expected;
 - (iii) a description of any benefits to the participant or others which may reasonably be expected;

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- (iv) a disclosure of any appropriate alternative procedures or courses of treatment, if any [, that might be advantageous for the person]; and
 - (v) an instruction that the person or surrogate is free to withdraw his or her consent at any time without prejudice.
- (3) No informed consent shall include any language through which the person or surrogate waives, or appears to waive, any legal right, including the release of any party, institution, agency, or any agents thereof, from liability from negligence.
- (4) Information must be presented in a manner permitting a knowledgeable evaluation and decision to be made. It must be presented in whatever language the party giving informed consent reads or understands most easily and clearly (e.g., English, Spanish, [German] Mandarin) and in whatever manner he or she understands most easily and clearly (e.g., sign language, communications board, computer assisted technology, Braille). Consent, when given by [another party] a surrogate, should only be given if, in doing so, this will be in the person's best interest and takes into consideration, to the extent possible, the person's opinions, beliefs, and wishes.
- (5) This definition does not apply to informed consent obtained by a subject party (see section 633.22 of this Part) related to criminal history record checks, as such consent is required pursuant to section 633.22 of this Part.
- (ax) Interest, best. Best interest shall mean promoting the person's well-being by evaluating the risks, benefits and alternatives to the person of a proposed treatment or intervention. Such a determination takes into account several factors including but not limited to the relief of suffering, the preservation or restoration of functioning, improvement in the quality of the person's life with and without the proposed treatment or intervention, and consistency with the personal beliefs and values known to be held by the person.
- (ci) Risk, undue. A level of risk that may affect a person's wellbeing, may involve a physical effect that changes the person's normal functional status or might be considered excessive by some third parties.
- (cs) Surrogate. For the purposes of sections 633.11, 633.16 and 633.18 of this Part, a party designated to act in the place of a person receiving services by the provisions of the respective regulations. For the purposes of section 633.13 of this Part only, someone designated to advocate on behalf of a person who may be/who will be the subject of research. Designation is made in conformance with section 633.13(a)(3)(ii)(b) of this Part.

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- **Section 681.13 is amended by the addition of new language immediately following the title of the section as follows:**

Between the effective date of Section 633.16 of this Title and the date specified in paragraph 633.16(a)(6), the requirements of this section are not effective with regard to behavior support plans which have been developed in accordance with Section 633.16 and with regard to informed consent that has been obtained in accordance with Section 633.16. On the effective date of Section 633.16, requirements concerning the specially constituted committee are no longer effective.

The requirements of this section are no longer in effect on or after the date specified in paragraph 633.16(a)(6) of this Title.