

**STATE OF CONNECTICUT  
DEPARTMENT OF DEVELOPMENTAL SERVICES**

**Procedure No. I.E.PR.003**  
**Subject: Behavior Modifying Medications**  
**Section: Health and Safety**

**Issue Date:** October 28, 2003  
**Effective Date:** Upon Release  
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**A. Purpose**

The purpose of this procedure is to ensure statewide consistency for the review and approval of the use of behavior modifying medications by individuals and to assure consistent implementation of Policy No. I.E.PO.003, Behavior Modifying Medications.

**B. Applicability**

This procedure applies to all individuals placed or treated under the direction of the Commissioner. This includes individuals receiving services in or from DDS operated, funded and/or licensed facilities, including ICF/MR, CLA, CTH, Day Services and DDS Individualized Home Supports provided in any setting and/or any DDS funded service regardless of where the individual lives. It applies to individuals receiving any HCBS Waiver Services where paid staff are required to carry out a behavioral intervention that utilizes an aversive, physical, or other restraint procedure and/or staff funded by the DDS who are required to pass/give a behavior modifying medication, regardless of where the individual lives. This procedure applies to individuals receiving services from the DDS Voluntary Services program if they are placed in an in-state DDS operated, funded and/or licensed facility. It also applies to any individuals who receive ongoing, planned psychiatric supports where behavior modifying medication is prescribed by the Psychiatrist regardless of where the individuals live and whether or not they are receiving DDS Waiver Services.

This procedure does not apply to those receiving DDS Respite Services only, those exempt from Program Review Committee/Human Rights Committee (PRC/HRC) review, and those who reside in long-term care facilities licensed, funded and/or overseen by other state agencies.

**C. Definitions**

Aversive Procedure: A procedure that contains the contingent use of an event or device which may be unpleasant, noxious, or otherwise cause discomfort to (1) alter the occurrence of a specific behavior or to (2) protect an individual from harming him or herself or others and may include the use of physical isolation and mechanical and physical restraint. This also includes the use chemical restraints and the use of restrictive procedures such as escorts (except escorts like 'guide along' that are met with little or no resistance from the individual), physical isolation, response cost, over-correction, restitution, and other similar techniques.

Behavior Modifying Medications: Any chemical agent used for the direct effect it exerts upon the central nervous system to modify thoughts, feelings, mental activities, mood, or performance. These chemical agents or psychotropic medications are often categorized as follows: antipsychotics (neuroleptics), antidepressants, antimanic, antianxiety agents, stimulants, and sedatives/hypnotics. Medications that are not usually described as psychotropics are covered by this procedure when they are prescribed primarily for their behavior modifying effects such as mood stabilization and impulse control. These medications include certain anticonvulsants, some beta-blockers, and certain other drugs.

Behavioral Support Plan: A written document developed to address an individual's behaviors that interfere with the implementation of the goals and objectives identified in the Individual Plan or to track and monitor target behaviors. The plan shall include identification of specific target behaviors and a plan for tracking and monitoring responses. When the use of aversive procedures to protect the individual from harming him or

herself or others is reasonably anticipated to be needed through the use of data, these specific procedures shall be included in the plan (see DDS I.E.PR.002 Behavior Support Plan).

Chemical Restraint: Psychotropic medications which are administered on a STAT or immediate basis in an emergency situation, usually after other interventions have failed to result in calm behavior and the individual is still in danger of harming him/herself or others. (This does not include medications used for pre-sedations for medical or dental procedures.)

DSM-IV (or subsequent editions): The American Psychiatric Association's Diagnosis and Statistical Manual of Mental Disorders, Fourth Edition (or subsequent editions), which is a widely-recognized and professionally-approved reference for the classification and diagnosis of mental disorders.

Emergency: An acute or urgent situation in which a physician has determined that treatment (i.e. medication) must be started immediately or a situation in which a caregiver determines that immediate intervention (i.e. emergency physical, mechanical and/or chemical restraint) is necessary to protect an individual from harming him or herself or others.

Exempt Process: A process defined in DDS I.E.PR.004, Program Review Committee (PRC) in which an individual who takes behavior modifying medications may request to be exempt from the PRC/HRC review process.

Extrapyramidal Symptoms: Abnormal muscle movements produced by neuroleptics' (antipsychotics') actions in the brain's extrapyramidal motor area.

Herbal Preparations, Vitamins, Mineral, Homeopathic Remedies: Products that are categorized as food supplements, are not drugs, and do not fall under the jurisdiction of the Federal Drug Administrations (FDA).

Human Rights Committee (HRC): A group of people who are not employees of the department, who provide monitoring to ensure the protection of legal and human rights of people with mental retardation. Membership may include a physician, a lawyer, a parent, staff of contracted agencies, and other volunteers. A DDS employee shall act as a liaison between the HRC and the region or training school. The HRC shall act as an advisory group to the regional or training school director.

Institutional Review Board (IRB): A group of individuals appointed by the commissioner to review and approve activities categorized as research involving human subjects where the research is either conducted, supported, or otherwise subject to regulation the DDS.

Monotherapy: The use of only one medication at one time.

Planning and Support Team (PST): Individuals and the people who are important in their lives. At the very minimum, all planning and support teams shall include the individual who is receiving supports, his or her guardian if applicable, and persons who the individual requests to be involved in the individual planning process including the individual's family and/or advocate, the individual's case manager and the support staff and others who know the individual best. Depending upon the individual's specific needs, professional staff who are providing supports and services to the individual may be involved in the individual planning process and in attendance at the individual planning meeting.

Polypharmacy: The use of two or more medications at one time. There are two types of polypharmacy:

Interclass Polypharmacy: The use of two or more medications from two or more different classes of medication (e.g., use of a neuroleptic with an antidepressant; the use of an antidepressant with an antianxiety agent, etc.).

Intraclass Polypharmacy: The use of two or more medications from the same class of medication (e.g. using two neuroleptics, two antidepressants, or two antianxiety agents, etc).

Positive Behavioral Supports: An integrated approach to teach an individual adaptive and socially appropriate skills and competencies. Supports may include teaching strategies and/or environmental supports to increase adaptive behaviors. These approaches should treat the individual in a respectful, age-appropriate manner, should be built into the individual's daily routine and should occur in a natural context. The individual and his or her family, guardian, advocate, and support staff should be involved in the design of the positive behavioral supports.

Prescriber: A person who is legally authorized to prescribe medications according to Chapter 380 of the Connecticut General Statutes. (APRN) and/or a physician's assistant (PA), preferably who has experience in mental retardation.

PRC/HRC Review: A Program Review Committee/Human Rights Committee review. The PRC review includes a member of the Human Rights Committee is present to represent and act on behalf of the Human Rights Committee.

PRC Liaison: A person selected by the Regional or Training School Director to act as the liaison between the PRC and the director, the department's central office, and all service providers.

Program Review Committee (PRC): A group of professionals, including a psychiatrist, assembled to review individual behavior treatment plans and behavior modifying medications to ensure that they are clinically sound, supported by proper documentation and rationale, and are being proposed for use in conformance with department policies. The PRC acts as an advisory group to the Regional or Training School director.

Tardive Dyskinesia: An abnormal movement disorder that may occur as an adverse reaction to the use of a neuroleptic (antipsychotic) medication. This syndrome is characterized by involuntary movements that may involve the tongue, face, mouth or jaw, trunk, or extremities.

## **D1 – Guiding Principles**

The need for a review and the length of the review cycle is determined by the Program Review Committee. Once the Program Review Committee has either checked the box 'PRC Review Not Required', or has established a review cycle, a Planning & Support Team/PST does not need to return to the PRC unless there is a change in diagnosis, significant change in medication type, significant change in medication dosage exceeding FDA range, or a significant increase in problem behaviors related to the use of medication.

### Behavior Modifying Medication

- A. If 2 or more Behavior Modifying Medications are utilized, or, even 1 anti-psychotic medication is utilized in treatment, then there must be an initial review by the Program Review Committee. Any future Program Review Committee review will be determined by the PRC.

- B. Behavior Modifying Medications that are utilized for any of the following treatments conditions would be exempt from the Program Review Committee process:
1. Mono-Therapies (Single Behavior Modifying Medication Utilized for clear diagnosis obtained from the treating 'prescriber' — These would include:
    - Depression
    - Anxiety Disorder
  2. Alzheimer's Medications
  3. Sleep Medications
  4. End Of Life Medications
  5. CP / Neurodegenerative Disorders Medications (Medications that are used solely for the treatment of disorders such as Cerebral Palsy, ALS, Muscular Dystrophy, or Multiple Sclerosis, etc.)
- C. Herbal Medications — Submit the one page "Attachment A - Request For PRC Date" form to Region. Your request for the use of the medication will be evaluated for the need for a PRC Review.

### Exemptions

Exempt criteria will be based on type and level of support for the person, specifically looking at how the individual manages their medical care. If a person has a guardian, they can be exempt if they meet the exempt criteria and the guardian approves. If a person does meet the exempt criteria, and there is no guardian, then the Planning & Support Team/PST for the person and the Regional Exempt Committee must agree on the exemption.

## **D2. Implementation**

1. A behavior modifying medication shall be used only under the conditions and process described below.
  - a. After observation and evaluation of the individual by the person's interdisciplinary team (PST), the team shall make a referral to the individual's physician or other prescriber for assessment.
  - b. If a medication is recommended, the prescriber shall provide a written order for the medication to the PST.
    - i. Following review at an PST meeting, a designated PST member shall obtain written consent for the use of the medication from the individual, parent or guardian. If this is not possible, a designated PST member shall:
      - (a) Send a copy of the medication plan and behavioral support plan to the individual, parent or guardian as applicable.
      - (b) Send a consent form to the individual, parent or guardian (as applicable) within 5 working days of the PST meeting.
      - (c) If possible, obtain telephone consent as soon as possible and subsequently obtain written consent as noted above.
    - ii. The medication shall not be started until consent is obtained except in circumstances described in 2(d)
  - c. The medication shall be used in conjunction with a comprehensive behavioral support plan that is part of the individual's Individual Plan of services.
  - d. The behavior modifying medication is prescribed only for a condition that is diagnosed according to the most current edition of The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM IV or subsequent edition) except that it shall not be prescribed solely for the diagnosis of mental retardation.

- e. The medication is approved by the Food and Drug Administration (FDA) except as noted in Section 3 (a-e) below.
  - f. Presenting symptoms, physical, neurological, environmental, and psychiatric causes have been considered as part of the decision to recommend the use of behavior modifying medication.
2. The use of a behavior modifying medication shall be reviewed and approved in accordance with DDS Policy I.E.PO.003, Program Review Committee and DDS Human Rights Committee, using the following process:
- a. When following PST referral and physician (or other prescriber) assessment, the physician/prescriber orders a new behavior modifying medication or orders a change in a current medication dose that exceeds previously reviewed and approved ranges (PRC & regional director), the prescriber shall develop and submit to the PST a medication plan that minimally includes:
    - i. A DSM-IV (or subsequent edition diagnosis of the drug-responsive condition being treated by the medication
    - ii. A description of physical or behavioral signs to be monitored for medication effectiveness
    - iii. Objective response criteria to the medication with timeframes and long and short term treatment goals
    - iv. A range in which the dosage may be adjusted to reach therapeutic levels
    - v. Expected duration of the use of the medication
    - vi. Possible unwanted side effects to be looked at for while the medication is in use and drug reactions and interactions with other supplemental preparations.
    - vii. The consequences of not administering the medication
    - viii. Other medications and dosage ranges within the same medication class that may be substituted in the event the originally prescribed medication proves ineffective
  - b. Administration of the medication shall begin upon consent of the individual/family/guardian as applicable and shall then be subject to review by the PRC and Human Rights Committee (HRC) processes. Consent shall be documented on the DDS Consent for Treatment form. (Attachment A) Consent forms shall be renewed annually.
  - c. If the PST assesses that the individual does not have the capacity to consent to the medication plan and the individual does not have a plenary guardian, a limited guardian for medical decisions, or conservator of person, the following shall occur:
    - i. The PST assure that the medication is not administered until receiving PRC/HRC review and regional/training school director approval unless the prescriber indicates that the medication must be started immediately.
    - ii. A PRC/HRC review shall be obtained using a temporary approval process that includes review by the regional director or designee, the PRC liaison and the HRC liaison or other designated manager.
    - iii. The PRC/HRC shall complete a full review at the next available PRC date.
  - d. If the individual, parent or guardian does not consent to the use of the medication, the medication shall not be started and the prescriber shall be notified. If the prescriber assesses that the individual is a danger to him/herself or others, a medication may be started without consent and
    - i. The medication plan shall be reviewed using the temporary approval process and receive a full review at the next scheduled PRC meeting, to which the individual/family/guardian is invited to attend.
    - ii. Following PRC/HRC review and regional or training school director approval, the PST shall again attempt to obtain consent for the medication.

- iii. If consent is not given, the individual/family/guardian shall be informed of their right to a hearing regarding this matter.
  - e. Staff members with appropriate training and experience shall write a behavior program that supports the individual's development and well-being in conjunction with the use of the medication. All programs shall include components designed to increase positive behavior. (See DDS, I.E.PR.002, Behavior Support Plans)
  - f. The individual's case manager or designated PST member shall notify the PRC liaison to schedule the PRC review as soon as possible using the Request for PRC form (see AttachmentB).
  - g. Upon notification of the PRC date, the individual's case manager or other designated staff shall ensure that the PRC packet is sent to the PRC liaison as detailed in DDS Procedure I.E.PR.004, Program Review Committee.
  - h. The case manager, author of the behavior program and/or other appropriate staff shall present the proposed medication plan and behavior program to the program review committee (PRC) if a presentation is required (See DDS I.E.PR.004, Program Review Committee).
  - i. The individual, parent, guardian or advocate may attend the PRC for the purpose of hearing the presentation and presenting any opposing views to the committee.
  - j. The PRC shall recommend approval, approval with qualifications or disapproval of the medication plan and behavior program to the regional or training school director. If the human rights committee representative objects to the recommendation of the PRC regarding the medication or the behavior program, a full HRC review shall be required prior to the recommendation of approval. The PRC may recommend to the regional or training school director that temporary approval be granted. Such temporary approval shall not exceed 60 days, during which time the HRC shall provide written recommendation to the PRC and the regional or training school director.
  - k. The regional or training school director shall approve, approve with qualifications or disapprove the medication plan and behavior program after considering the recommendations of the PRC and the HRC. If the regional or training school director decides to approve a medication plan despite the PRC/HRC recommendation for disapproval, the reason for the approval along with the behavior program and the committees' recommendations shall be sent to the commissioner. The commissioner must concur with the program approval before it may be implemented.
  - l. A copy of the medication plan and behavior support plan along with all reviews and signatures shall be placed in the individual's file.
3. While DDS policy respects an individual's right not to be subjected to experimentation (i.e., research), such participation may be in an individual's best interest. If the use of a medication is part of a research or investigational study, the following actions shall occur:
- a. Research or investigational studies may be reviewed by the department's Institutional Review Board (IRB) as detailed in Policy: II.G.PO.001, Office of the Commissioner Institutional Review Board Policy.
  - b. Following review and approval by the IRB, adults who are capable of giving informed consent and have not been adjudicated as needing a plenary or medical guardian, may consent to their own participation in the approved project.
  - c. The research has been approved by the probate court in accordance with CGS 45a-677.

- d. Children (individuals under age 18) may participate with the consent of their parents.
  - e. Individuals who have a guardian (plenary or medical) must have approval in accordance with Section 45a-677 as amended by PA 01-140 and PA 02-58, which state that a guardian may consent if the research is approved by a recognized IRB according to Federal Law (non-DDS) and endorsed or supported by the DDS (DDS, IRB).
  - f. If the research of investigational study includes the use of a non-FDA approved medication, a licensed nurse or physician must administer the medication.
4. Whenever possible, the use of monotherapy is encouraged. Polypharmacy may be appropriate based on documented treatment rationale and current standards of practice.
    - a. Intraclass polypharmacy involving the use of two neuroleptics (antipsychotics) is prohibited except:
      - i. During the medically-supervised change-over from one medication to another within this class
      - ii. Upon prescriber documentation of rationale including drug history, risk versus benefit analysis, and other pertinent information
      - iii. When such treatment meets recognized standards of practice as documented in the literature
    - b. Intraclass polypharmacy involving other classes of behavior modifying medications (classes other than neuroleptics) shall be reviewed for appropriate psychiatrist rationale and currently accepted standards of practice
  5. A behavior modifying medication shall be administered:
    - a. By licensed nurses or by DDS Certified staff (certified in accordance with Sections 17a-210-1 to 17a-210-9 of the Regulations of Connecticut State Agencies (Medication Administration Regulations),
    - b. Only as prescribed by a legally authorized prescriber, and
    - c. Only by a licensed nurse or physician when the medication is not FDA approved and is being used as part of an approved research or investigational study
  6. A behavior modifying medication shall not be prescribed on a PRN or as needed basis except in rare instances. These exceptions shall be approved by the regional or training school director following a review and recommended approval by the PRC/HRC based on submitted documentation that minimally includes:
    - a. A rationale for the treatment plan;
    - b. Methods for monitoring the use of the medication;
    - c. Clear criteria for the administration of the medication and;
    - d. Other appropriate safeguards as determined by the PST, PRC and/or HRC.
    - e. Orders shall be time-limited and shall be scheduled for re-review as specified by the PRC based on the specific situation defined in the plan.
  7. A behavior modifying medication may be prescribed on a STAT or at once basis. Standing orders for the use of chemical restraints are prohibited.
  8. The PST shall review the effects of the behavior modifying medication quarterly. This review shall address positive responses as well as any potentially undesirable side effects such as extra-pyramidal symptoms and shall be reported to the prescriber.

9. The prescriber shall see the individual, review and re-order the behavior modifying medication or as determined by the prescriber but not to exceed 180 days except where more stringent regulations apply (i.e., ICF/MR).
10. The prescriber shall see the individual and assess for abnormal involuntary movement prior to initiation of a neuroleptic medication and every six months thereafter, and shall document the assessment as detailed in DDS Medical Advisory #2002, Monitoring for Abnormal Involuntary Movements (Tardive Dyskinesia).
11. When clinically appropriate, the prescriber in conjunction with the PST shall develop a plan to reduce and/or discontinue the use of the medication within a specified period of time.
12. An individual who is competent to make medical decisions, has not been adjudicated incompetent, lives independently with minimal assistance may request to be exempt from the PRC/HRC review. The exemption process is delineated in the PRC procedures: I.E.PR.004, Program Review Committee.
13. The use of behavior modifying medication as part of terminal end of life care may:
  - a. Be exempt from PRC review if:
    - i. an individual has been certified by their physician and the Hospice Medical Director (or designee) to be terminally ill and have six months or less to live if the identified illness runs its normal course and
    - ii. the individual receives care from an approved Hospice program.
    - iii. if the individual lives longer than six months the exemption may still be appropriate as long as the physician and Hospice Medical Director (or designee) determine hospice care should continue.
  - b. not be exempt if:
    - i. the individual's health improves or illness is in remission and the individual no longer requires hospice care, PRC review will be required.
14. Medications prescribed to improve cognitive function of an individual diagnosed with dementia of the Alzheimer's type are not reviewable unless they are prescribed concomitantly with other behavior modifying meds.
15. Medication ordered for sleep disturbances associated with a medical diagnosis are not reviewable unless they are prescribed to treat a specific target behavior associated with an active psychiatric diagnosis in accordance with I.E. PR. 004.
16. An herbal preparation, vitamin, mineral, homeopathic remedy or other similar food supplement ordered for its behavior modifying effects for a specific target behavior, shall be reviewed by PRC/HRC as delineated in DDS procedure I.E. PR.004, Program Review Committee.
17. When an individual moves from one living situation to another, the receiving PST shall convene within 30 days to develop an Individual Plan of service. If this plan includes behavior modifying medications

that currently have approval from any regional or training school director, and are ordered by the new physician, the approval shall remain valid and the following shall occur:

- a. The PST shall notify the appropriate DDS PRC liaison of the decision to continue the approved medications.
- b. If the individual's move was to another DDS region, the receiving PRC liaison will ensure that the next PRC/HRC review date is scheduled as close as possible to the re-review date identified by the sending region's PRC.
- c. If the receiving physician/prescriber ordered different medications or dosages with consent of the individual/family/guardian, a full PRC/HRC review shall be required as soon as possible by the receiving PRC. If the individual does not have the capacity to consent and he/she does not have a guardian, the PST shall follow the procedure detailed in section 2(d)(1-3).
- d. If the individual has moved from a long-term care facility, the receiving region shall schedule a full PRC/HRC review of any behavior modifying medication as soon as possible.
- e. If the use of behavior modifying medication has not been reviewed or if any regional or training school director had disapproved it, a full PRC/HRC review shall be scheduled as soon as possible by the receiving region.

#### **E. PRC and Psychiatric Medication Data Review**

The Department of Developmental Services (DDS) is responsible for monitoring the use of behavior modifying medications. This is done in a variety of ways: the Program Review process, Interim Approval process, and the Psychotropic Medication Monitoring process. All of this information is entered into the DDS internal data system ( eCAMRIS ).

The DDS Central Office is responsible for compiling statewide reports analyzing the following areas: PRN use of behavior modifying medications, use of two or more neuroleptic medications, timeliness of Tardive Dyskinesia ( TD ) screening, Psychiatrist/Prescriber review, and PRC review within 36 months. IN order to ensure accuracy the following shall occur:

1. Psychiatric diagnosis (DSM-IV or subsequent editions), behavior modifying medications, aversive programs, tardive dyskinesia screenings and PRC review dates shall be documented in eCAMRIS after the initial review.
2. Each proceeding PRC review will prompt a review of the data in eCAMRIS, data will be updated to reflect the current behavior modifying medications, aversive programs, tardive dyskinesia screenings and PRC review date.
3. Psychotropic medication data collected in eCAMRIS will be reviewed annually.
  - a. Each year starting in January, DDS central office will print out a list by Provider, identifying the site, and each individual located at that service site, listing the medication code, the psychotropic medication, and the dosage.
  - b. This list will be sent to the provider, who will review for accuracy, make appropriate edits, and return to the DDS regional designee or RN assigned to the division.
  - c. These reports must be returned to the appropriate region within 90 calendar days.
  - d. Once the report is received by the Region, eCAMRIS will be updated within 90 days.
  - e. It is important that the providers note if a medication was discontinued and the date.

## **F. References**

CT General Statute 17a-210  
CT General Statute 17a-238  
CT General Statute 19a-469  
CT General Statute 45a-677  
CT General Statute 45a-677(e)  
CT General Statute 46a-11 et seq.  
ICF/MR Federal Regulations 483-420, “Condition of Participation, Client Protections”  
ICF/MR Federal Regulations 483-440, “Condition of Participation, Active Treatment Services”  
ICF/MR Federal Regulations 483-450, “Condition of Participation, Client Behavior and Facility Practices”  
DDS I.F.PO.001, Abuse and Neglect Prevention  
DDS I.F.PR.001- Abuse and Neglect Prevention, Reporting, Notification, Investigation, Resolution and Follow-up  
DDS, I.E.PO.002, Behavior Support Plans  
DDS, I.E.PR.002, Behavior Support Plans  
DDS I.E.PO.004, Program Review Committee  
DDS, I.E.PR.004, Program Review Committee  
DDS, I.E.PR.006, Pre-sedation for Medical/Dental Procedures  
DDS, II.G.PO.001, Office of the Commissioner Institutional Review Board (IRB)  
DDS.II.G.PR.001, Office of the Commissioner Institutional Review Board (IRB)

DDS I.F.PO.006, Human Rights Committee  
DDS Policy 7, Programmatic Administrative Review  
DDS I.C.1-4, Case Management Policies & Procedures  
DDS Policy 13, Advocates

## **G. Attachments**

Attachment A: Consent for Treatment form  
Attachment B: Request for PRC to Review Behavior Modifying Medication and/or Aversive Procedure