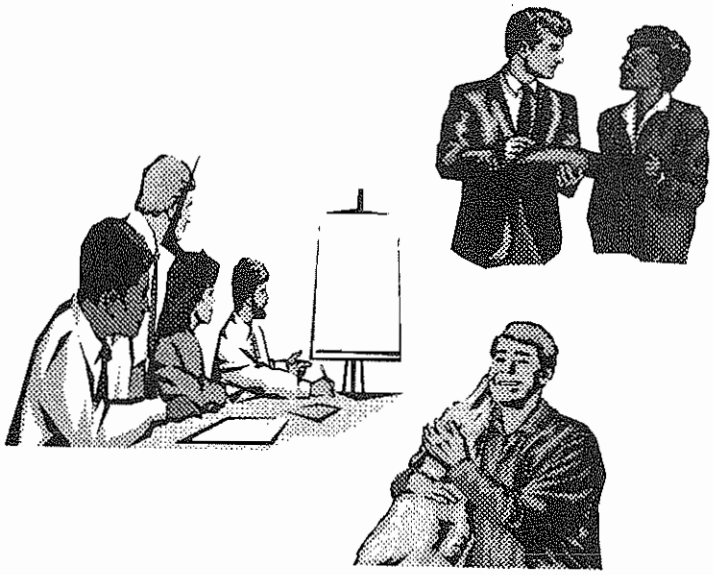
PSYCHOPHARMACOLOGICAL MEDICATIONS

Safety Precautions for Persons with Developmental Disabilities



A Resource for Training and Education

By the
Health Care Financing Administration
Health Standards and Quality Bureau
Center for Long Term Care

NOTE: Although the Social Security Act refers to Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), and uses the term "mentally retarded"; most now prefer the terms "Facilities for Persons with Developmental Disabilities" and "Persons with Developmental Disabilities".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

Dear ICF/MR Administrator:

We are sending you this document, entitled "Psychopharmacological Medication, Safety Precautions for Persons with Developmental Disabilities; A Resource for Training and Education" to assist you and your staff in increasing the benefit from psychopharmacological medications while minimizing the harm that they sometimes can cause. We are sending "Safety Precautions" to the Administrators of all Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) and all State survey agencies.

These "Safety Precautions" have been developed over a period of years by the Health Standards and Quality Bureau with input from physicians and pharmacists who have experience and training with persons who suffer from developmental disabilities and mental illness. These "Safety Precautions" represent common sense steps for protecting your clients from the sometimes significant and long lasting adverse drug reactions from psychopharmacological medications. Please give these "Safety Precautions" serious consideration.

The use of psychopharmacological medications can be therapeutic and empowering for someone who is suffering from mental illness. Therefore, the primary goal of these "Safety Precautions" is to encourage the accurate differential diagnosis of behavioral and psychiatric symptoms so that the person's treatment is appropriate.

But psychopharmacological medications should not be used when a behavioral disturbance is caused by an environmental stressor (e.g., excessive heat, noise, overcrowding, etc.), a psychosocial stressor (e.g., abuse, taunting, teasing, etc.), or a treatable non-psychiatric medical condition (e.g., heart disease, diabetes, hypothyroidism, etc.). **All** facility staff should search for the basic cause or reason for behavioral or psychiatric symptoms and endeavor to treat the basic cause or reason in the least intrusive most positive way.

These "Safety Precautions" may also alert the State agency surveyor to a situation when a psychopharmacological medication should be used when it is not. For example, a person may be suffering from symptoms of depression (e.g., withdrawal behavior, crying, etc.), yet has never been evaluated for the condition of depression and the possible use of psychopharmacological medications. While surveyors are not trained as psychiatrists, they should be alert to this potential situation and should be ready to encourage compliance with 42 CFR 483.460(a)(3) which requires the facility to arrange or provide for preventive or general physician care. Hopefully, this care is provided by a psychiatrist or a practitioner who is in consultation with a psychiatrist.

Although psychopharmacological medications were once used to sedate persons with developmental disabilities, today many facilities around the country use more enlightened practices. Psychiatrists with knowledge and experience in treating persons with developmental disabilities can more accurately diagnose and effectively treat mental illness in people with developmental disabilities. However, the differentiation of signs representing mental illness from behavioral disturbance or other conditions where treatments other than the use of psychopharmacological medications may be appropriate often remains a difficult task because persons with developmental disabilities frequently do not have verbal language skills.

The need for knowledge in this field is the fundamental reason the Nisonger Center convened an International Consensus Conference on Psychopharmacology in June, 1995, at The Ohio State University. The Conference proceedings, an extensive consensus from the best minds in the fields of psychopharmacology and developmental disabilities, discuss general principles of differential diagnosis in persons with developmental disabilities who suffer from mental illness and include chapters on each major category of psychopharmacological medication. The proposed title of these proceedings is Psychotropic Medication and Developmental Disabilities: The International Consensus Handbook. This consensus document will be published and available in early 1997. To obtain this handbook, write or call:

Nisonger Center
The Ohio State University
1581 Dodd Drive
Columbus, Ohio 43210-1296
Phone: (614) 292-8365
Fax: (614) 292-3727

The "Safety Precautions" in this document focus on surveyor and provider education and the relationship between principles of psychopharmacological and the regulations governing participation of facilities in the Medicaid program. These "Safety Precautions" are compatible with the Nisonger Handbook. The use of both will serve to build practices, skills, and experiences that will create a safer and more empowering environment for persons with developmental disabilities. For these reasons we hope that you will give these "Safety Precautions" your careful consideration.

If you have any questions about the "Safety Precautions" please refer them to Dr. Samuel W. Kidder, at (410) 786-6795. And please help us by completing the evaluation form following this letter.

Sincerely,

Richard W. Besdine, M.D.
Director
Health Standards and Quality Bureau

HCFA
MEDICARE • MEDICAID
Health Care Financing Administration

PROVIDER EVALUATION

Psychopharmacological Medications: **Safety Precautions** for Persons with Developmental Disabilities

A Resource for Training and Education

After you have read the "**Safety Precautions,**" please complete this evaluation. This evaluation may be copied and given to others in your facility for comment. If you, or any staff, have additional comments or insights, please add these to the evaluation.

I. Have you shared, or do you plan to share, these "**Safety Precautions**" with:
(If any categories do not apply, please respond with "**N/A** ".)

	Yes	No	
A.	____	____	Your **direct care staff**?
B.	____	____	The **Qualified Mental Retardation Professional** (QMRP)?
C.	____	____	The **nurses** who serve your client(s)?
D.	____	____	The **physicians** who serve your client(s)?
E.	____	____	The **specially constituted committee**?
F.	____	____	The **interdisciplinary team**?

II. Will you use these "**Safety Precautions**" to conduct inservice training for:
(If any categories do not apply, please respond with "**N/A**".)

	Yes	No	
A.	____	____	Your **direct care staff**?
B.	____	____	The **Qualified Mental Retardation Professional** (QMRP)?
C.	____	____	The **nurses** who serve your client(s)?
D.	____	____	The **physicians** who serve your client(s)?
E.	____	____	The **specially constituted committee**?
F.	____	____	The **interdisciplinary team?**

III. Do you think that these "**Safety Precautions**" will help you:

	Yes	No	
A.	____	____	identify clients who *may be* in need of psychopharmacological medications?
B.	____	____	identify clients who are experiencing adverse effects from psychopharmacological medications?

_____FOLD

C.	____	____	identify clients' behavioral disturbances that *may be caused* by the adverse effects of psychopharmacological medications?
D.	____	____	identify changes in environmental or psychosocial circumstances that would be less restrictive and more positive interventions for your clients' behavioral disturbances than the use of psychopharmacological medications?

IV. What state is your facility located in?

_____

Thank you for the time and thought you have given in completing this evaluation of "**Safety Precautions**". Please fold this page in thirds, seal it, and mail it to:

_____FOLD

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Samual W. Kidder, Pharm.D., MPH
HSQB, Center for Long Term Care
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S2-20-03
7500 Security Boulevard
Baltimore MD 21244-1850

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PART I.

General Safety Precautions for Psychopharmacological Medications

For a facility to use psychopharmacological medications with optimal safety, it should adhere to the **General Safety Precautions** in this section and the **Specific Safety Precautions** unique to the medication categories in **Part II**.

General Safety Precautions for Psychopharmacological Medications in ICFs/MR

1. **Rule Out Other Causes**
2. **Collect Baseline Data**
3. **State a Reasonable Hypothesis**
4. **Intervene in the Least Intrusive and Most Positive Way**
5. **Monitor for Adverse Drug Reactions (ADRs)**
6. **Collect Outcome Data**
7. **Start Low and Go Slow**
8. **Periodically Consider Gradual Dose Reduction**
9. **Maintain Active Treatment Objectives**
10. **Maintain Optimal Functional Status**

The Surveyor should apply these **General Safety Precautions** to all categories of psychopharmacological medications in **Part II**. An explanation of each **General Safety Precaution** follows.

1. Rule Out Other Causes

Before beginning psychopharmacological medication, the facility has substantial information to demonstrate that it considers and rules out other reasons such as medical, environmental, or psychosocial causes for the behavioral or psychiatric symptom.

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an accurate and comprehensive functional assessment.
42 CFR 483.440(c)(4) requiring an individual program plan . . . to meet the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh the potentially harmful effects of the drug.

2. Collect Baseline Data

Before beginning psychopharmacological medication, the facility has substantial information to demonstrate that it collects baseline data* on specific objectively defined target behaviors or psychiatric symptoms for a sufficient time** of two to four weeks.

If the person has recently been transferred to the facility and baseline data is not available, the facility does not have to remove the person from the psychopharmacological medication to obtain baseline data. Instead the facility should try to obtain the baseline data from the previous facility **if possible*** and begin collecting new data with the current psychopharmacological medication at the current dose to evaluate subsequent changes.

* In determining the baseline, the facility should use a recognized objective data collection method such as a frequency count, duration recording, time sample, interval recording, rating scale, or some combination involving these methods.

** If the facility uses a shorter time period, it must have justifying documentation which ensures, at a minimum, that variables such as transitory outbursts ("a bad day"), the environment, or illness have not resulted in a deceptively high or an unrepresentative rate of the occurrence of signs or symptoms.

*** It may not always be possible to obtain baseline data from the previous facility due to factors such as the person or guardian refusing to release such information or the previous facility failing to collect such information.

One **Exception** to this **General Safety Precaution** is the collecting of baseline data for recurrent behaviors. Refer to the box on the next page.

Exception: Baseline Data for Recurrent Behaviors

If outcome data is available to show that previous treatment was successful,
and the outcome data was collected in the person's current environment,
and no major changes* have occurred within that environment,
and the behavior recurs within six months;

Then previously collected baseline data may be used for the recurrent behavior
and the facility does not have to collect new baseline data.

* Examples of major changes are where the person's daily activity schedule has been significantly reorganized, where behavioral or psychiatric or active treatment programs have been revised, etc.

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an assessment.
42 CFR 483.440(c)(4) requiring an individual program plan to deal with the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

3. State a Reasonable Hypothesis

The facility has stated a reasonable hypothesis of the underlying cause of the behavioral or psychiatric symptoms. This hypothesis includes the relationship or rationale between the person's symptoms and how the prescribed psychopharmacological medication will treat these symptoms to achieve the desired outcome.

REGULATORY BASIS:
42 CFR 483.450(e)(2) requiring that medications only be used when an integral part of an individual program plan directed specifically toward reduction or elimination of behaviors for which the medications are used.

4. Intervene in the Least Intrusive and Most Positive Way

The facility has substantial information to demonstrate that it attempted the least intrusive and most positive interventions* to manage behavioral or psychiatric symptoms before it considered using psychopharmacological medication.

* Examples of least intrusive and most positive interventions are active treatment programs incorporating psychotherapy or educational programs specific to the presenting problem, and positive reinforcement procedures and other learning and behavior modification procedures such as
- antecedent analyses
- fading
- forward or backward chains
- shaping
- specific program steps with criteria levels for advancement or remedial branching
- stimulus control
- task analysis

See **Definitions**.

Note: PSYCHOPHARMACOLOGICAL MEDICATION

Initially, the least intrusive and most positive intervention to treat behavioral or psychiatric symptoms may be the use of a psychopharmacological medication.

However,

all **General** and **Specific Safety Precautions** should be applied

and

once the symptoms are managed, non-psychopharmacological active treatment programs specific to the behavior or psychiatric condition should be started within a reasonable period* of time.

* A reasonable period of time is one to four weeks unless the facility justifies a longer period.

REGULATORY BASIS:
42 CFR 483.450(b)(1)(iii) requiring least restrictive most positive interventions.

5. Monitor for Adverse Drug Reactions (ADRs)

The facility has substantial information to demonstrate that it adequately monitors* for adverse drug reactions. If ADRs do occur, the facility has substantial information to show why the ADR is not significantly impairing the person's functional status or quality of life or why the psychopharmacological medication is not changed, discontinued, or decreased in dose.

* The term "adequately monitors" includes the periodic assessment of the person with a standardized side effects rating scale or checklist such as the
  - Adverse Drug Reaction (ADR) Detection Questionnaire, **or**
  - Monitoring of Side Effects Scale (MOSES), **or**
  - Systematic Assessment for Treatment of Emergent Effects (SAFTEE), **or**
  - Dosage Record and Treatment Emergent Symptom Scale (DOTES).

  See **Definitions**.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

6. Collect Outcome Data

The facility has substantial information, including quality of life information, to demonstrate that it determines and supports with objective data that the psychopharmacological medication achieves the desired outcome. Objective data includes the use of a recognized data collection method* for the person's target behavior(s) or psychiatric symptom(s) and comparison to the available baseline data.

* In determining the outcome, the facility should use a recognized data collection method such as a frequency count, duration recording, time sample, interval recording, rating scale, or some combination of these methods. See **Definitions**.

REGULATORY BASIS:
42 CFR 483.450(e)(2) requiring that medications only be used when an integral part of an individual program plan directed specifically toward reduction or elimination of behaviors for which the medications are used.

7. Start Low and Go Slow

The facility has substantial information to demonstrate that it uses low initial and maintenance doses of psychopharmacological medication commensurate with age, weight, and symptomatology to achieve the desired outcome, minimize adverse drug reactions, and maintain optimal functional status.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring lowest possible dose.

8. Periodically Consider Gradual Dose Reduction

The facility has substantial information to demonstrate that **unless clinically contraindicated** it periodically attempts to gradually reduce the dose of psychopharmacological medication to determine if the person's behavioral or psychiatric symptoms can be treated with a lower dose or whether the psychopharmacological medication can be discontinued altogether. Any attempt to reduce the dose should be coordinated with the interdisciplinary team, in a carefully monitored program.

The **Exception** to this **General Safety Precaution** is the diagnosis of epilepsy. When the person is diagnosed with epilepsy, **do not** apply this **General Safety Precaution**. Instead apply the **Specific Safety Precaution, "Reassess the Need for the AED after Two Years of Seizure Free Therapy"**, on page 45.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisplinary team, unless clinically contraindicated.

9. Maintain Active Treatment Objectives

The facility has substantial information supported with objective data to demonstrate that the psychopharmacological medication is not causing the person to regress or to fail to progress in achieving the stated objectives in the individual program plan in comparison with measurements taken before and after psychopharmacological medication is started.

REGULATORY BASIS:
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status".
42 CFR 483.440(f)(1)(i),(ii), and (iii) requiring an annual review of the client's progress in achieving individual program plan objectives.

10. Maintain Optimal Functional Status

The facility has substantial information, supported with objective data, to demonstrate that the psychopharmacological medication is **not diminishing** the person's functional status from his/her baseline functional status measures. See **Definitions** for the definition of functional status. Also see page 50, "Loss of Functional Status".

REGULATORY BASIS:
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status."

Two terms, "substantial information to demonstrate" and "clinically contraindicated" were used frequently in this section. These terms are explained here. Other significant terms used throughout the **General** and **Specific Safety Precautions** are explained under **Definitions**.

What does "substantial information to demonstrate" mean?

"Substantial information to demonstrate" does not simply mean that the order for the psychopharmacological medication includes a diagnostic label. "Substantial information to demonstrate" means that the physician has a valid clinical reason for using this psychopharmacological medication as evidenced by your evaluation of some, but not necessarily all, of the following:

- data on specifically defined target behaviors
- individual assessment
- interview of the direct care staff, family, other residents, and similar information
- plan of care
- laboratory reports
- medication orders
- observation and interview with the client
- professional consultations
- progress notes
- reports of significant change

What does "clinically contraindicated" mean?

"Clinically contraindicated" means that the facility:

a. provides a description of previous gradual dose reduction failures **or**

b. fully supports why the continued use of the psychopharmacological medication and the dose of the psychopharmacological medication is clinically appropriate and not clinically contraindicated as demonstrated by the following four elements:

1. **Symptomatology** is a thorough description of individual symptoms and not simply a diagnostic label or a diagnostic code.

2. **Differential Diagnosis** is a discussion of the differential medical symptoms, including psychiatric symptoms. For example, why is the person's aggression part of a psychosis and not the result of pain or of psychosocial and environmental stressors?

3. **Choice of Treatment** is a description of the reasoning for the choice of a particular treatment or treatments.

4. **Dose Level** is a discussion of why the present dose is necessary to manage the person's symptoms.

PART II.

SPECIFIC SAFETY PRECAUTIONS

FOR

CERTAIN CATEGORIES

of

PSYCHOPHARMACOLOGICAL

MEDICATIONS

Note: For the purposes of this document the **generic** drug name is used first followed by the **trade** name in parenthesis, for example: diazepam (Valium).

PART II

Specific Safety Precautions for Certain Categories of Psychopharmacological Medications

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1. What Are Benzodiazepine Medications?

Benzodiazepine (ben-zoe-dye-AZ-e-peen) medications belong to the group of medicines called central nervous system (CNS) depressants. CNS depressants are medications that lower the activity of the central nervous system. For example, CNS depressants reduce alertness and cognition. Benzodiazepine medications are used for various conditions such as anxiety, panic disorder, epilepsy, insomnia (sleepnessness), and muscle spasms. Each of these conditions is discussed below:

Anxiety. Some benzodiazepine medications are classified as anxiolytic (anxiety-decreasing) medications. The following benzodiazepine medications are primarily used to relieve anxiety or nervousness.

Generic Name:	chlordiazepoxide	diazepam	lorazepam	oxazepam
Trade Name:	Librium	Valium	Ativan	Serax

Another benzodiazepine medication, alprazolam (Xanax), is used to treat panic disorder. **Panic disorder** is a unique form of anxiety.

Epilepsy. Although there is little evidence that benzodiazepine medications are effective for the long term treatment of epilepsy in most individuals, in some cases certain benzodiazepine medications are used in treating epilepsy. For further information about epilepsy and the medications used to treat it, see pages 41 and 42, "**4. Epilepsy and the Use of Antiepileptic Drugs**" and "**5. Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy**".

Insomnia (sleeplessness). The benzodiazepine medications are usually not effective for insomnia for more than a few weeks. The following benzodiazepine medications are used in the treatment of insomnia.

Generic Name:	flurazepam	temazepam	triazolam
Trade Name:	Dalmane	Restoril	Halcion

Muscle Spasm. Some benzodiazepine medications are also used for muscle spasms. Diazepam (Valium) is used to relax muscles or to relieve muscle spasm.

2. Anxiety

a. What Is Anxiety ?

An anxiety disorder may manifest itself as a behavioral or a psychiatric symptom. Anxiety can be a symptom for a wide variety of non-psychiatric medical problems such as cardiac ischemia or ulcers.

Stedman's Medical Dictionary defines anxiety as follows: "Apprehension of danger and dread accompanied by restlessness, tension, tachycardia, and dyspnea unattached to a clearly identifiable stimulus." Note that in this definition, the individual has clear physiological symptoms such as tachycardia (fast heart rate) or dyspnea (shortness of breath) and that these symptoms occur without any clear reason. The origin or cause for these physiological symptoms are especially difficult to determine in people with nonexistent or limited verbal language skills. This is why the first **General Safety Precaution**, **"Rule Out Other Causes"**, is particularly important in persons with developmental disabilities.

b. Anxiety and the Use of Benzodiazepine Medications

Before considering the use of any medication for anxiety, it is **essential to evaluate the medical, psychosocial, and environmental causes for anxiety**. There are times when it is appropriate for a person to be anxious. For example, if a person is being abused or humiliated, it is not appropriate to use medication to make the person less anxious and more compliant with abuse. Failure to evaluate causes such as these makes the use of benzodiazepine medications, or any other medications for anxiety, inappropriate.

Often, anxiety is treated well without medications. However, treatment may require a combination of both pharmacologic and non-pharmacologic interventions. Medications can easily be overused if a person does not have a comprehensive intervention program for anxiety which includes relaxation, appropriate counseling, and/or reduction of environmental stress.

c. Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to benzodiazepine medications used for anxiety.

1. **Monitor for Adverse Drug Reactions (ADRs) from the Benzodiazepine Medication Used for Anxiety**

2. **Screen for Higher Doses of the Benzodiazepine Medication Used for Anxiety**

3. **Consider Gradually Reducing the Dose of the Benzodiazepine Medication Used for Anxiety**

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.

Three **Exceptions** to these **Specific Safety Precautions** are explained on pages 21 and 22.

1. Monitor for Adverse Drug Reactions (ADRs) from the Benzodiazepine Medication Used for Anxiety

The facility has substantial information to demonstrate that it adequately monitors the person for any adverse drug reaction (ADR) from a benzodiazepine medication used for anxiety. If these ADRs do occur, the facility has substantial information to demonstrate why the ADR does not significantly impair the person's functional status or quality of life or why the medication was not changed, discontinued, or decreased in dose.

Adverse Drug Reactions (ADRs) from Benzodiazepine Medications

- Continuing Slurred Speech
- Decreased Reflexes
- Disinhibition (Lack of Impulse Control)
- Dysphagia (Difficulty in Swallowing)
- Hyperactivity
- Shortness Breath or Trouble Breathing
- Impaired Learning
- Persistent Confusion
- Severe Drowsiness
- Severe Weakness
- Staggering / Falls

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

2. Screen for Higher Doses of the Benzodiazepine Medication Used for Anxiety

The facility has a reasonable explanation that justifies why doses **greater** than those listed in the screen below are necessary to improve or maintain the person's functional status.

SCREEN FOR HIGHER DOSES OF BENZODIAZEPINE MEDICATIONS USED FOR ANXIETY

These dose levels are given to establish a point at which higher doses should be explained. If the person is prescribed a higher dose than shown, the facility should explain the specific clinical circumstances requiring the higher dose.

GENERIC	TRADE	DAILY ORAL DOSE* (in milligrams)	
		Adults	Geriatric or Child under 12
alprazolam	Xanax	2	1
chlordiazepoxide	Librium	40	20
clonazepam	Klonopin	3	1.50
clorazepate	Tranxene	30	15
diazepam	Valium	20	10
halazepam	Paxipam	100	40
lorazepam	Ativan	6	2
oxazepam	Serax	60	30
prazepam	Centrax	30	15

* **These are not maximum doses!** When higher doses are prescribed, the facility should explain in the clinical record the unique circumstances which require the higher dose.

Appropriate clinical doses vary greatly depending on the individual signs or symptoms, age, weight, and other factors. Doses lower than these are often adequate to achieve the desired outcome for the person.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring the lowest possible dose.

3. Consider Gradually Reducing the Dose of the Benzodiazepine Medication Used for Anxiety

The facility has substantial information to demonstrate that **unless clinically contraindicated*** it periodically attempts to gradually** reduce the dose of the benzodiazepine medication to determine if the person's behavioral or psychiatric symptom can be helped with a lower dose, or to determine if the medication can be discontinued altogether.

The facility should attempt to reduce the dose of benzodiazepine medication, in a carefully monitored program, within **four** months or less of therapy, and at least annually thereafter, **unless clinically contraindicated**. This attempt should be coordinated with the interdisciplinary team in a carefully monitored program.

* **Clinically contraindicated** is defined on page 9.

** Gradually reducing the dose is **especially important** in withdrawal of benzodiazepine medications because rapid reductions may result in more serious withdrawal symptoms. Gradual dose reduction is generally accomplished by reducing the dose by 25% every 1 to 4 weeks depending on the duration of the dose, age, symptoms, weight, and other factors.

Adhering to this recommendation for dose reduction is **even more important** if the person has been using a short-acting benzodiazepine medication in a high dose for an extended period of time.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisciplinary team, unless clinically contraindicated.

d. Exceptions to the Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety

When a benzodiazepine medication is used for the following conditions, it should not be reviewed under the **Specific Safety Precautions** unique to benzodiazepine medications used for anxiety, page 17.

1. **Dental, Medical, or Surgical Procedures**
2. **Muscle Spasm**
3. **Seizure Disorder or Status Epilepticus**

Exception 1: Dental, Medical, or Surgical Procedures

These **Specific Safety Precautions** do not apply when the medication is given in a single dose to relieve anxiety or to produce amnesia before a dental, medical, or surgical procedure.

Exception 2: Muscle Spasm

These **Specific Safety Precautions** do not apply if diazepam (Valium) or clonazepam (Klonopin) is used to treat muscle spasm. If one of these medications is used to treat a muscle spasm, the clinical record should substantiate that the person has a condition such as:

1. **muscle spasm** secondary to inflammation of muscles or joints or trauma,
2. **spasticity** caused by upper motor neuron disorder such as cerebral palsy or paraplegia,
3. **tardive dyskinesia** caused by antipsychotic medications, or
4. **athetosis.**

If the condition is **not** substantiated in the clinical record, or the dose is being changed based on behavioral or psychiatric symptoms, then **presume** that the medication is being used to treat an anxiety disorder and apply the "**Specific Safety Precautions for Benzodiazepine Medications Used for Anxiety**" on page 17.

Exception 3: Seizure Disorder or Status Epilepticus

These **Specific Safety Precautions** do not apply if diazepam (Valium), chlorazepate (Tranzene), lorazepam (Ativan), or clonazepam (Klonopin) is being used to treat seizure disorder or status epilepticus. If seizure disorder or status epilepticus is being treated, follow the "**Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy** " on page 42.

3. INSOMNIA

a. What Is Insomnia?

Insomnia is the inability to sleep in the absence of external impediments such as noise, or bright lights, during a period of time that one normally sleeps. Insomnia is not necessarily a pathological circumstance. Everyone occasionally has difficulty in sleeping. There are many causes of insomnia and many approaches to treatment.

The long term use of benzodiazepine medication and other hypnotic drugs to treat transient insomnia can result in dependency. The term "hypnotic" means sleep inducing. The key to managing insomnia is to:

1. **Rule out all causes of insomnia**. See page 26.

2. Follow good sleep hygiene practices. See "**For a Good Night's Sleep**" on the following page.

3. Refrain from using hypnotics for transient insomnia.

4. When a hypnotic must be used, only use it for a short period of time.

For a Good Night's Sleep z z z

z z z z z z z z z z z z z....

☺ DO ☺

Exercise today, but not too late in the evening ☺

Develop a sleep ritual ☺

Go to bed at your usual time every night ☺

Relax before bedtime by reading or taking a hot bath ☺

Sleep in a cool, dark, quiet bedroom ☺

Wake up at the usual time every morning ☺

☹ DO NOT ☹

Take naps during the day ☹

Drink alcoholic beverages or smoke, especially near bedtime ☹

Consume beverages with caffeine: coffee, or tea and many soft drinks, especially near bedtime ☹

Eat foods that contain caffeine, such a chocolate ☹

Go to bed stuffed or starved ☹

Go to bed too early☹

Adapted from "*The Good Night Guide*", © 1993, with permission of The Better Sleep Council.

b. Insomnia and Use of Benzodiazepine and Other Medications

Any benzodiazepine medication and many antihistamines, whether marketed as a hypnotic (sleep-inducing) medication or not, can be used to induce sleep. For the generic and trade names of benzodiazepine medications and other sleep inducing medications, please refer to page 28, "**Screen for Higher Doses of Benzodiazepine And Other Medications Used for Insomnia**".

c. Specific Safety Precautions for Benzodiazepine and Other Medications Used for Insomnia

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to benzodiazepine and other medications used for insomnia.

1. **Rule Out Other Causes for Insomnia**
2. **Collect Baseline Data on the Occurrence of Insomnia**
3. **Manage Insomnia in the Least Intrusive and Most Positive Way**
4. **Monitor for Adverse Drug Reactions (ADRs) from the Medication Used for Insomnia**
5. **Screen for Higher Doses of the Medication Used for Insomnia**
6. **Periodically Consider Gradually Reducing the Dose of the Medication Used for Insomnia**

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.

1. Rule Out Other Causes for Insomnia

The facility has substantial information to demonstrate that other causes for insomnia have been ruled out. These include but are not limited to:

- use of certain medications and substances,
- medical conditions such as asthma, pain, and sleep apnea,
- psychiatric conditions such as anxiety, bipolar disorders, and depression
- environmental conditions, such as cold, heat, light, and noise

Many medications and substances will cause insomnia. If a person is taking one or more medications that causes insomnia, then this medication needs to be evaluated to determine if it can be discontinued, changed to another medication that does not cause insomnia, or reduced in dose. The person may need to discontinue or reduce the use of some substances. Some commonly used medications and substances that cause insomnia are:

1. Alcohol, Caffeine, Nicotine, Theophylline, Tobacco
2. Antidepressant medications such as Prozac, Paxil, Zoloft.
3. Decongestants such as Sudafed and Actifed.
4. Beta-Blockers such as propranolol. (See page 58.)

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an assessment.
42 CFR 483.440(c)(4) requiring an individual program plan to deal with the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

2. Collect Baseline Data on the Occurrence of Insomnia

The facility has substantial information to demonstrate that, unless a shorter period of time is justified, baseline data* on insomnia should be collected by objective information or data for at least two to four weeks. See page 4, **Part I, General Safety Precaution #2.**

* The facility has specific data and analysis documenting if the characteristics of the sleep disorder which include the inability to initiate sleep, inability to maintain sleep, early morning awaking, etc.. This analysis includes review of any antecedents to the insomnia including disputes with staff or other people, visit by a relative, etc.), or medical conditions (e.g., pain, fever, infection, etc.)

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an assessment.
42 CFR 483.440(c)(4) requiring an individual program plan to deal with the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

3. Manage Insomnia in the Least Intrusive and Most Positive Way

Before it prescribes benzodiazepine or other medications for a person's insomnia; the facility has substantial information to demonstrate that it has tried the least intrusive and more positive interventions, such as exercise, abstinence from afternoon naps, or regular sleep periods and that these interventions are a part of the individual treatment plan.

REGULATORY BASIS:
42 CFR 483.450(b)(1)(iii) requiring least restrictive most positive interventions.

4. Monitor for Adverse Drug Reactions (ADRs) from the Medication Uses for Insomnia

The facility has substantial information to demonstrate that it adequately monitored for the following adverse drug reactions (ADRs) in the box below. If these ADRs do occur, the facility has substantial information to show why the ADR does not significantly impair the person's functional status or quality of life or why the medication was not changed, discontinued, or decreased in dose.

Adverse Drug Reactions (ADRs) from Benzodiazepine Medications

- Continuing Slurred Speech
- Decreased Reflexes
- Disinhibition (Lack of Impulse Control)
- Dysphagia (Difficulty in Swallowing)
- Hyperactivity
- Shortness Breath or Trouble Breathing
- Impaired Learning
- Persistent Confusion
- Severe Drowsiness
- Severe Weakness
- Staggering / Falls

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

5. Screen for Higher Doses of the Medication Used for Insomnia

The facility has a reasonable explanation such as severe symptoms or significant body weight that supports why doses **greater** than those listed in the screen below are necessary to improve or maintain the person's functional status.

SCREEN FOR HIGHER DOSES OF BENZODIAZEPINE AND OTHER MEDICATIONS USED FOR INSOMNIA

These dose levels are given to establish a point at which higher doses should be explained. If the person is prescribed a higher dose than shown, the facility should explain the specific clinical circumstances requiring the higher dose.

GENERIC	TRADE	DAILY ORAL DOSE* (in milligrams) Adults	Geriatric or Child under 12
alprazolam	Xanax	0.50	0.25
chloral hydrate**	Noctec**	1000	500
estazolam	ProSom	1	0.50
flurazepam	Dalmane	30	15
lorazepam	Ativan	2	1
oxazepam	Serax	30	15
quazepam	Doral	15	7.50
temazepam	Restoril	30	7.50
triazolam	Halcion	0.25	0.125
zolpidem**	Ambien**	10	5

* **These are not maximum doses!** When higher doses are prescribed, the facility should explain in the clinical record the unique circumstances which require the higher dose.

Appropriate clinical doses vary greatly depending on the individual signs or symptoms, age, weight, and other factors. Doses lower than these are often adequate to achieve the desired outcome for the person.

** Not a benzodiazepine medication.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring the lowest possible dose.

6. Periodically Consider Gradually Reducing the Dose of the Medication for Insomnia

The facility has substantial information to demonstrate that, **unless clinically contraindicated***, it periodically attempted to gradually** reduce the dose of the medication for insomnia to determine if the person's insomnia can be managed with a lower dose or whether the medication can be discontinued altogether.

The facility should attempt to reduce the dose of the medication for insomnia, in a carefully monitored program, within **14 days or less** of therapy, and then at least **annually** thereafter, **unless clinically contraindicated**. This attempt should be coordinated with the interdisciplinary team in a carefully monitored program.

* **Clinically contraindicated** is defined on page 9.

** Gradually reducing the dose is **especially important** in withdrawal of benzodiazepine medications because rapid reductions may result in more serious withdrawal symptoms. Gradual dose reduction is generally done by reducing the dose by 25% every 1 to 4 weeks depending on the duration of the dose, age, symptoms, weight, and other factors.

Adhering to this recommendation for dose reduction is **even more important** if the person has been using a short-acting benzodiazepine medication in a high dose for an extended period of time.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisciplinary team, unless clinically contraindicated.

4. Barbituates and Other Medications Used for Anxiety and/or Insomnia

Medications in this category have significant potential for habituation. Among these medications are barbiturates and other miscellaneous hypnotic and sedative medications. Examples are given in the box below.

Barbiturates

Generic Name	Trade Name
amobarbital	Amytal
amobarbital-secobarbital	Tuinal
barbiturates with other medications	e.g., Fiorinal
butabarbital	Butisol
pentobarbital	Nembutal
phenobarbital	Many Brands
*primidone	*Mysoline
secobarbital	Seconal

* Primidone (Mysoline) converts to phenobarbital in the body.

Other Medications Used for Anxiety and Insomnia

Generic Name	Trade Name
ethchlorvynol	Placidyl
glutethmide	Doriden
meprobamate	Equinal, Miltown
methprylon	Noludar
paraldehyde	Many Brands

Because newer, safer medications are now available, **initiating** the use of these medications, by the facility should be considered **unnecessary** drug use.
See page 31. An **Exception** is explained on page 33, after the **Specific Safety Precautions**.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

a. Specific Safety Precautions for Barbituates and Other * Medications Used for Anxiety or Insomnia

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to barbituates and other medications * used for anxiety or insomnia.

1. **Do Not Initiate Barbituates and Other Medications***

2. **Gradually Reduce the Dose of Barbituates and Other Medications***

3. **Give the Newly Admitted Person Time to Adjust**

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.

* For a list of the "**Other Medications**", see those listed in the box **on** page 30.

1. Do Not Initiate Barbituates and Other Medications

When the facility **initiates** the use of the medications listed in box on page 30 for people, this use should be viewed as **unnecessary** drug use. For an **Exception** , phenobarbital in the treatment of epilepsy, see page 33.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

2. Gradually Reduce the Dose of Barbituates and Other Medications *

For a person currently using barbituates or other medications* for anxiety or insomnia, the facility should gradually reduce the dose to minimize any potential dependency on the medication. (Note the **exception** for epilepsy on page 33.) Unless clinical evidence indicates that such gradual dose reduction is **clinically contraindicated****, the facility should attempt to gradually reduce the dose of the medication at least **once a year**. This attempt should be coordinated with the interdisciplinary team, in a carefully monitored program.

These medications often cause adverse drug reactions such as those shown in the box below.

Adverse Drug Reactions (ADRs) from Barbituates and Other Medications*

aggressive behavior	cognitive loss
behavioral or psychiatric disturbances	hyperactivity
central nervous system (CNS) depression	self injury

* For "**Other Medications**", see those listed in the box on page 30.

** **Clinically contraindicated** is defined on page 9.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisciplinary team, unless clinically contraindicated.

3. Give the Newly Admitted Person Time to Adjust

Before the facility attempts to gradually reduce the dose of barbituates or other medications, it should give the newly admitted person who is using the medication time (about 30 to 90 days) to adjust to the changes in her/his environment.

b. Exception to Specific Safety Precautions for Barbituates and Other Medications * Used for Anxiety or Insomnia

Exception: Epilepsy

These **Specific Safety Precautions** unique to barbituates and other medications * used for anxiety and insomnia do not apply to phenobarbital or primidone (Mysoline)* * when it is used to treat **epilepsy**; however, phenobarbital and primidone are no longer considered first-line drugs in treating epilepsy for these reasons:

- In children, phenobarbital and primidone (Mysoline) **
  - cause paradoxical hyperactivity.
  - *may* suppress cognition and IQ development.
- In adults, phenobarbital and primidone (Mysoline)**
  - cause central nervous system depression.
  - *may* cause cognitive impairment, and behavioral or psychiatric disturbances.
- In people with developmental disabilities, phenobarbital and primidone (Mysoline)**
  - *may* cause exacerbation (worsening) of existing problems such as self-injurious behavior, aggression, etc.

* For "**Other Medications**", see those listed in the box on page 30.

** Primidone (Mysoline) converts to phenobarbital when in the body.

A. Benzodiazepine, Barbituates, Other Medications for Anxiety, Insomnia

B. Antiepileptic Medications Used for Epilepsy or Behavioral or Psychiatric Conditions

1. What Is Epilepsy? 36

2. Behavioral or Psychiatric Symptoms and the Use of Antiepileptic Drugs (AEDs) 36

3. Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Behavorial or Psychiatric Symptoms 38

4. Epilepsy and the Use of Antiepileptic Drugs (AEDs) 41

5. Specific Safety Precautions for Antiepileptic Drugs(AEDs) Used for Epilepsy 42

1. What Is Epilepsy?

Epilepsy is a periodic **recurrence** of seizures with or without convulsions. A single seizure does not constitute a diagnosis of epilepsy. Epilepsy encompasses a group of syndromes that are further classified by type of seizure, presence or absence of convulsions, and maintenance or loss of consciousness. Seizures occur when a few (five to 10) neurons (nerve cells) in the brain fire abnormally and cause adjoining neurons in the brain to do the same. The type and severity of seizure determines appropriate drug therapy and other treatment modalities.

In about 70% of the people with epilepsy, the cause is unknown. Some known causes of epilepsy are trauma, brain toxins (from poisoning or infections), or congenital defects. Some events such as sleep deprivation, sensory stimulation, and stress trigger seizures but most occur unpredictably. Seizures generally occur when there is an increase in the number of chemical transmitters that stimulate neurons or when there is a deficiency in chemical transmitters that inhibit neurons. Drug therapy is directed at restoring this balance.

2. Behavioral or Psychiatric Symptoms and the Use of Antiepileptic Drugs (AEDs)

Antiepileptic drugs (AEDs) are sometimes used to treat behavioral or psychiatric symptoms because:

- Reports indicated that carbamazepine (Tegretol) improved the psychiatric symptoms of patients with epilepsy
- There is a chemical similarity between carbamazepine (Tegretol) and tricyclic antidepressants (e.g., Elavil, Norpramin). Although several studies support this association, it is not universally accepted.

Because these AEDs are used to treat symptoms such as aggression and destructive or self-injurious behavior with what many believe may to be a high degree of effectiveness, the surveyor should have some knowledge and basis for determining whether the proper **Specific Safety Precautions** are followed when these medications are used either for treatment of epilepsy or for behavioral or psychiatric symptoms. Before making a determination about **Specific Safety Precautions**, the surveyor should learn why the AED is being prescribed. The information in the following box should be helpful in making this decision.

Is the Antiepileptic Drug (AED) Used for a Behavioral or Psychiatric Symptom?

The surveyor can determine if a person is being treated for epilepsy or for a behavioral or psychiatric symptom by assessing the person and her/his clinical history.

IF there is an **absence** of evidence * of a history of recurrent seizures (epilepsy) in the clinical record,
and
behavioral or psychiatric symptoms are present,
and
an AED is used;

THEN presume that the AED is being used for behavioral or psychiatric symptoms
and
follow the "**Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Behavorial or Psychiatric Symptoms**" on the next page.

* For example, the clinical record lacks:

- Documentation of the observation of recurrent seizures and/or seizure counts.
- A description of the circumstances surrounding the seizure such as
  - arm and leg movements and/or rigidity,
  - loss of consciousness,
  - the duration of the seizure,
  - a confirmation of the seizure through an electroencephalogram (EEG), **if possible**, or other evidence.

3. Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Behavioral or Psychiatric Symptoms

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to behavioral or psychiatric symptoms and the use of AEDs.

1. **Behavioral or Psychiatric Symptom Is Part of an Affective Disorder**

2. **Monitor the Blood Level and Specific Baseline and Laboratory Functions for the AED**

3. **Do NOT Use Phenobarbital, Phenytoin, or Primidone for Behavioral or Psychiatric Symptoms**

4. **Monitor for Adverse Drug Reactions (ADRs) from the AED**

1. Behavioral or Psychiatric Symptom Is Part of an Affective Disorder

The facility has substantial information to demonstrate that the behavioral or psychiatric symptom is a part of an affective disorder (such as, mania, bipolar disorder, or schizoaffective disorder) or has documentation justifying why the AED is used in the absence of an affective disorder.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

2. Monitor the Blood Level and Specific Baseline and Annual Laboratory Determinations for the AED

The facility has substantial information to demonstrate that it carefully monitors the drug therapy as indicated by the following:

a. Documented determination of the **blood level** of the AED, if one has been established for the AED being used, when:

(1) the therapeutic effect is not being achieved, or

(2) potential adverse drug reactions are present, or

(3) the dose is being changed, or

(4) there are additions or deletions of medications that could alter blood levels.

b. Documented **specific baseline** and, at least, **annual** laboratory determinations of:

(1) **Blood Count:** Complete blood count on all AEDs **except** gabapentin (Neurontin) and lamotrigine (Lamictal).

(2) **Liver:** Hepatic function studies on all AEDs **except** gabapentin (Neurontin), and lamotrigine (Lamictal).

(3) **Kidney:** Renal function studies on gabapentin (Neurontin) only.

(4) **Electrolyte:** Sodium electrolyte determinations for carbamazepine (Tegretol) only.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

3. Do NOT Use Phenobarbital, Phenytoin (Dilantin), or Primidone (Mysoline) for Behavioral or Psychiatric Symptoms

The facility has substantial information to demonstrate that it does **not** use phenobarbital, phenytoin (Dilantin) or primidone (Mysoline) to treat behavioral or psychiatric symptoms.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

4. Monitor for Adverse Drug Reactions from the AED

The facility has substantial information to demonstrate that it adequately monitors for, and identifies, adverse drug reactions (ADRs) from AEDs. If an ADR occurs, the facility has documentation showing why the ADR did not significantly impair the person's functional status or why the drug was not changed, discontinued, or decreased in dose.

Refer to the box below for those ADRs to be monitored.

Adverse Drug Reactions (ADRs)
from
Antiepileptic Drugs (AEDs)

Ataxia (failure of muscle coordination)
Behavioral or Psychiatric ADRs*
Decline in Learning Ability
Decline in Memory
Drowsiness
Dysarthria (imperfect articulation of speech)
Dysphagia (difficulty in swallowing)
Headache
Nystagmus (involuntary rapid movement of the eyeball)
Psychomotor Excitation** or Restlessness
Rash
Sedation

* Such as agitation, irritability, hyperactivity, etc.
** Defined on page 74.

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication excerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

4. Epilepsy and the Use of Antiepileptic Drugs (AEDs)

Is the Antiepileptic Drug (AED) Used for Epilepsy?

The surveyor can determine if a person is being treated for epilepsy or for a behavioral or psychiatric symptom by assessing the person and her/his clinical history.

IF there is **evidence** * of a history of recurrent seizures (epilepsy) in the clinical record,
and
an AED is used;

THEN presume that the person is being treated for recurrent seizures
and
follow the "**Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy**" on the next page.

* For example, the clinical record shows:

- Documentation of the observation of recurrent seizures and/or seizure counts.
- A description of the circumstances surrounding the seizure such as
  - arm and leg movements and/or rigidity,
  - loss of consciousness,
  - the duration of the seizure,
  - a confirmation of the seizure through an electroencephalogram (EEG), **if possible**, or other evidence.

5. Specific Safety Precautions for Antiepileptic Drugs (AEDs) Used for Epilepsy

Apply all **General Safety Precautions, except # 8***, listed in **Part I** and these **Specific Safety Precautions** unique to epilepsy and the use of AEDs.

1. **Obtain an Electroencephalogram (EEG)**
2. **Avoid Polypharmacy**
3. **Monitor for Blood Level and Specific Baseline and Laboratory Functions for the AED**
4. **Monitor for Adverse Drug Reactions (ADRs) from the AED**
5. **Reassess the Need for the AED After Two Years of Seizure Free Therapy***
6. **Periodically Consider Gradually Reducing the Dose of Phenobarbital and Primidone**

* **General Safety Precaution # 8. "Periodically Consider Gradual Dose Reduction"**, on page 8, is **NOT** applied if the symptoms described in the clinical record support the person's diagnosis of epilepsy. Instead apply **Specific Safety Precaution # 5. "Reassess the Need for the AED After Two Years of Seizure Free Therapy"**.

1. Obtain An Electroencephalogram (EEG)

The facility has substantial information to demonstrate that it made good faith efforts to obtain a electroencephalogram (EEG) which could, but does not always, confirm the diagnosis of epilepsy. If the facility is unable to provide an EEG report, this does not mean the diagnosis is inaccurate. However, the absence of an EEG should make the surveyor skeptical of the diagnosis and purpose of the use of an AED.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

2. Avoid Polypharmacy

The facility has substantial information to demonstrate that it has avoided the use of more than one AED. The use of two or more AEDs may be necessary, but the use of polytherapy significantly complicates the management of the drug therapy with multiple adverse drug reactions, drug interactions, etc.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."
42 CFR 483.450(e)(4)(i) requiring the close monitoring of drug therapy.

3. Monitor the Blood Level and Specific Baseline and Annual Laboratory Determinations for the AED

The facility has substantial information to demonstrate that it carefully monitors the drug therapy as indicated by the following:

a. Documented determination of the **blood level** of the AED, if one has been established for the AED being used, when:

(1) the therapeutic effect is not being achieved, or

(2) potential adverse drug reactions are present, or

(3) the dose is being changed, or

(4) there are additions or deletions of medications that could alter blood levels.

b. Documented **specific baseline** and, at least, **annual** laboratory determinations of:

(1) **Blood Count:** Complete blood count on all AEDs **except** gabapentin (Neurontin) and lamotrigine (Lamictal).

(2) **Liver:** Hepatic function studies on all AEDs **except** gabapentin (Neurontin), and lamotrigine (Lamictal).

(3) **Kidney:** Renal function studies on gabapentin (Neurontin) only.

(4) **Electrolyte:** Sodium electrolyte determinations for carbamazepine (Tegretol) only.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh harmful effects of the drug.

4. Monitor for Adverse Drug Reactions (ADRs) from the AED

The facility has substantial information to demonstrate that it adequately monitors for, and identifies, adverse drug reactions (ADRs) from AEDs. If an ADR occurs, the facility has documentation showing why the ADR did not significantly impair the person's functional status or why the drug was not changed, discontinued, or decreased in dose.

Refer to the box below for those ADRs to be monitored.

Adverse Drug Reactions (ADRs)
from
Antiepileptic Drugs (AEDs)

Ataxia (failure of muscle coordination)
Behavioral or Psychiatric ADRs*
Decline in Learning Ability
Decline in Memory
Drowsiness
Dysarthria (imperfect articulation of speech)
Dysphagia (difficulty in swallowing)
Headache
Nystagmus (involuntary rapid movement of the eyeball)
Psychomotor Excitation** or Restlessness
Rash
Sedation

* Such as agitation, irritability, hyperactivity, etc.
** Defined on page 74.

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication excerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

5. Reassess the Need for the AED After Two Years of Seizure Free Therapy

If the person has been on an AED **and** has been free from seizures for two years, the facility should have the individual reassessed for the continued need for such therapy.

REGULATORY BASIS:
42 CFR 483.460(a)(3)(iii) requiring physicians' services, including special studies, when needed.

6. Periodically Consider a Gradual Dose Reduction for Phenobarbital and Primidone * (Mysoline)

The Facility Has Substantial Information to Demonstrate That . . .

IF a person is taking phenobarbital or primidone* (Mysoline) for epilepsy **and** is displaying disruptive behavior, the facility

- **considers** adding another AED ** and gradually reducing the dose of phenobarbital or primidone (Mysoline) until, eventually, it is discontinued; or
- provides written justification showing why the disruptive behavior **does not** represent adverse drug reactions from the phenobarbital or primidone (Mysoline); or
- explains why it is not possible to discontinue phenobarbital or primidone (Mysoline).

This Is Especially Important . . .

- **IF** another psychopharmacological medication such as an antianxiety or antipsychotic medication, is also being used to treat disruptive behavior, or
- **IF** an **intensive** behavioral program is in place to treat disruptive behavior.

How to Reduce the Dose of Phenobarbital and Primidone* (Mysoline) . . .

Unless the Phenobarbital or Primidone (mysoline) is **used for only a very short period of time**, not more than two (2) weeks; the dose should be gradually reduced over a time period of eight (8) weeks or more.

* Primidone (Mysoline) converts to phenobarbital in the body.

** **Be alert** for cummulative adverse drug reactions.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . .and are provided active treatment to reduce dependency on drugs . . . ."
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually unless clinically contraindicated.

C. Antipsychotic Medications

1. What Is Psychosis? 48

2. Antipsychotic Medications Used for Behavioral or Psychiatric Symptoms 48

3. Specific Safety Precautions for Antipsychotic Medications Used for Behavioral or Psychiatric Symptoms 49

4. Exception to the Specific Safety Precautions 56

1. What Is Psychosis?

Psychosis is defined as the presence of one or more of the following symptoms: delusions, hallucinations, disorganized speech, grossly disorganized behavior, and negative symptoms such as flat affect or emotional withdrawal.

For a complete definition of the various types of psychosis see the Diagnostic Statistical Manual of Mental Disorders, Fourth Edition, (DSM-IV) of the American Psychiatric Association.

2. Antipsychotic Medications Used for Behavioral or Psychiatric Symptoms

Antipsychotic medications are those medications that are primarily used to treat psychosis. When antipsychotic medications are used to treat behavioral disturbances, their use may or may not be appropriate. If the person is experiencing behavioral disturbances caused by symptoms of psychosis, then the use of the antipsychotic medications **is** appropriate provided that the symptoms are being relieved. When antipsychotic medications are used to treat behavioral disturbances which are not caused by one of the symptoms of psychosis, then these medications are inappropriate and **may** be considered **unnecessary** drugs under 42 CFR 483. 420(a)(6).

Criteria for Treating Psychosis

Symptoms of psychosis **must be persistent**
and
must cause harmful behavior
or
must cause functional loss,

Before the use of an **antipsychotic medication is necessary**.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that ICFs/MR "Ensure that people are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

3. Specific Safety Precautions for Antipsychotic Medications Used for Behavioral or Psychiatric Symptoms

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to antipsychotic medications.

1. **Rule Out Other Causes for the Symptoms that May Represent Psychosis**

2. **Inappropriate Use of the Antipsychotic Medication**

3. **Periodically Consider Gradually Reducing the Dose of the Antipsychotic Medication**

4. **Monitor for Adverse Drug Reactions (ADRs) from the Antipsychotic Medication**

5. **Use an Antiparkinsonism Medication Only When Necessary**

6. **Screen for Higher Doses**

The greater the inability of the facility to follow each **General** and **Specific Safety Precaution**, the greater the potential risk of harm to the person being treated, and the greater the propensity for the surveyor to judge the drug therapy as unnecessary. If the **General** and **Specific Safety Precautions** are **not** followed, offer the facility an opportunity to explain why it was unable to carry out these protection activities.

The **Exception** to these **Specific Safety Precautions** is explained on page 56.

1. Rule Out Other Causes for the Symptoms that May Represent Psychosis

Before the facility uses an antipsychotic medication, it should have substantial clinical information to demonstrate that there are **clear indications** for the use of an antipsychotic medication. These indications for the use of an antipsychotic medication are explained on the following page in the box titled, "**Indications for the Use of an Antipsychotic Medication**".

For an understanding as to what experiencing functional loss means, refer to "**Loss of Functional Status**" in the box below.

Loss of Functional Status

Loss of Functional Status or Functional Loss is defined as a **measurable loss** of a person's previously possessed ability to function in one or more of the following ways:

→ Activities of Daily Living (e.g., locomotion, bathing, dressing, eating, etc.)

→ Cognition or Thinking (especially in memory and orientation)

→ Communication

→ Continence, Bladder or Bowel

→ Motivation and Interest in Preferred Activities

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

Indications for the Use of an Antipsychotic Medication

EITHER

I. The person **must** have
   A. **Specific** and **persistent** symptoms which cause
      1. **functional loss**, or
      2. **physical harm** to her/himself or others
   B. These **specific symptoms** include one or more of the following:
      1. Delusions
      2. Disorganized Speech
      3. Grossly Disorganized Behavior
      4. Hallucinations
      *5. Negative Symptoms of Schizophrenia

OR

II. The person **must** have **specific** and **persistent** physically harmful behaviors** **not** associated with a psychosis but reasonably associated with a behavioral--pharmacological hypothesis which may respond to antipsychotic medication.

UNDER EITHER CIRCUMSTANCE

III. The facility should have substantial information to document that these symptoms **cannot be explained by other causative factors** such as:
   1. Environmental factors (e.g., heat, cold, noise, etc.)
   2. Medical factors (e.g., pain, fatigue, urinary tract infection, cardiac ischemia, etc.)
   3. Other psychiatric conditions that require different treatment (e.g., anxiety, depression, etc.), **or**
   4. Psychosocial factors (e.g., abuse, taunting by peers, excessive standards of performance, disruptive behaviors from others, etc.)

* Examples of **negative symptoms of schizophrenia** are difficulty in abstract thinking, emotional withdrawal, flat affect, poor rapport, etc.

** These behaviors **must be specifically documented** with baseline data, which must be collected for a sufficient period of time using a recognized method for data collection. Refer to page 4, **General Safety Precaution, "2. Collect Baseline Data ".**

2. Inappropriate Use of the Antipsychotic Medication

The facility has substantial information to demonstrate that the antipsychotic medications are **not** used to deal with the following behaviors when that behavior is the only symptom present:

- → agitation
- → anxiety
- → depression without symptoms of psychosis
- → fidgeting
- → impaired memory
- → indifference to surroundings
- → insomnia
- → nervousness
- → restlessness
- → uncooperativeness
- → unsociability
- → wandering

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

3. Periodically Consider Gradually Reducing the Dose of the Antipsychotic Medication

The facility has substantial information to demonstrate that **unless clinically contraindicated*** it periodically attempts to gradually** reduce the dose of the antipsychotic medication and determine if the person's behavioral or psychiatric symptom(s) can be managed with a lower dose, or whether the drug can be discontinued altogether.

The facility should attempt to reduce the dose of the antipsychotic medication in a carefully monitored program **within six months or less** of therapy, and at least **annually** thereafter, **unless clinically contraindicated**. This attempt should be coordinated **with the interdisciplinary team**.

* **Clinically contraindicated** is defined on page 9.

** Unless an extremely low dose of the antipsychotic medication is prescribed, or a serious adverse effect is present, "gradual dosage reduction" of an antipsychotic medication is generally accomplished by reducing the dose by 10% to 25% once every 1 to 3 months depending on the length of the medication therapy, its dose level, individual symptoms, age, weight, and other factors.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring the close monitoring of drug therapy.
42 CFR 483.450(e)(4)(ii) requiring a gradual dose reduction at least annually in a carefully monitored program . . . with the interdisciplinary team. unless clinically contraindicated.

4. Monitor for Adverse Drug Reactions (ADRs) from the Antipsychotic Medication

The facility has substantial evidence that it adequately monitored for the adverse drug reactions (ADRs) from antipsychotic medications shown in the following box. If these ADRs do occur, the facility has substantial information to show why the ADR does not significantly impair the person's functional status or quality of life or why the drug was not changed, discontinued, or decreased in dose.

Adverse Drug Reactions (ADRs) from Antipsychotic Medications

Anticholinergic (ACH) (e.g., dry mouth, blurred vision, constipation)

Cognitive/ Behavior Impairment

Extrapyramidal (including Akathisia, Parkinsonism, and Dystonia)

Postural (orthostatic) Hypotension

Sedation / Lethargy

Tardive Dyskinesia*

* Monitoring for the ADR of Tardive Dyskinesia is defined as the use of a standardized assessment device and examination procedure, for example, the **AIMS** or **DISCUS** tests, at least once every six months.

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

5. Use an Antiparkinsonism Medication Only When Necessary

The facility has substantial information to demonstrate that antiparkinsonism medications are used to treat extra-pyramidal adverse drug reactions (ADRs) of antipsychotic medications **only** when these extrapyramidal ADRs are clearly demonstrated, **unless a clinical rationale** for such drug therapy is provided (e.g., to prevent dystonias in the first few weeks of antipsychotic medication therapy). Also, such medication is **not recommended** beyond three to six months without justification for its continued need. Justification includes the use of a standardized assessment device and examination procedure, for example, use of the Simpson-Angus neurological rating scale at least once every 6 months.

Extrapyramidal ADRs are usually manifested by movement disorders that include Dystonia, Akathisia, and Parkinsonism.

Antiparkinsonism Medications Used to Treat Extrapyramidal Adverse Drug Reactions (ADRs) from Antipsychotic Medications

Generic Name	Brand Name
amantadine	Symmetrel
benzodiazepines	See lists.*
benztropine	Cogentin
biperiden	Akineton
carbodopa, levodopa	Sinemet
diphenhydramine	Benadryl
procyclidine	Kemadren
propranolol	Inderal
trihexyphenidryl	Artane

* See lists on pages 19 and 28.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "Ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."

6. Screen for Higher Doses

The facility has substantial information to demonstrate why doses of antipsychotic medications higher than those listed in the "Screen for Higher Doses" on the next page are necessary to maintain or improve the person's functional status. This explanation should be supported by factual clinical data available in the facility.

Screen for Higher Doses of Antipsychotic Medications when taken by Persons with Mental Retardation

These dose levels are given to establish a point at which higher doses should be explained. If the person is prescribed a higher dose than shown, the facility should explain the specific clinical circumstances requiring the higher dose.

Generic	Trade	Daily Oral Dose* (in milligrams)
chlorpromazine	Thorazine	500
fluphenazine Decanoate	Prolixin Decanoate**	25 every 3 weeks
fluphenazine	Prolixin, Permitil	15
trifluprazine	Vesprin	75
thioridazine	Mellaril	500
perphenazine	Trilafon	48
trifluoperazine	Stelazine	25
chlorprothixene	Taractan	300
thiothixene	Navane	32
haloperidol	Haldol	15
	Haldol Decanonate**	100 every 4 weeks
molindone	Moban	100
loxapine	Loxitane	100
clozapine	Clorazil	500
risperidone	Risperdal	6
mesoridazine	Serentil	250

* **These are not maximum doses!** When higher doses are prescribed, the facility should explain in the clinical record the unique circumstances which require the higher dose.

Appropriate clinical doses vary greatly depending on the individual signs or symptoms, age, weight, and other factors. Doses lower than these are often adequate to achieve the desired outcome for the person.

** These are **injections**, not oral doses.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requires that "The facility must not use medications in doses that interfere with the individual client's living activities".

4. Exception to the Specific Safety Precautions

Exception: Conditions Sometimes Treated with an Antipsychotic Medication

An antipsychotic medication is also sometimes used to treat the conditions listed below. The **Specific Safety Precautions** unique to antipsychotic medications are not applied if one of these conditions are substantiated in the clinical record:

- Huntington's Disease
- moderate to severe pain in some hospitalized patients
- nausea
- severe hiccups
- symptoms of Tourette's Syndrome
- vomiting

D. Beta-Blockers Sometimes Used for Aggressive Behaviors

(Beta-Blockers, also called Beta-Adrenergic Blocking Agents)

1. What Are Beta-Blockers ? 58

2. Beta-Blockers Sometimes Used for Aggressive Behavior 58

3. Specific Safety Precautions for Beta-Blockers Sometimes Used for Aggressive Behavior 59

1. What Are Beta-Blockers ?

Medications that block nerve impulses at the beta-adrenergic receptor site are referred to as beta-adrenergic blocking agents or "beta-blockers" for short.

Adrenergic nerves are those nerves activated by adrenalin. (Adrenalin is also known as epinephrine.) Adrenergic nerves have two main receptors. One is known as the "alpha-adrenergic receptor". The other is known as the "beta-adrenergic receptor". Since beta-adrenergic receptors are important for proper heart functioning and artery constriction and relaxation, beta-blockers are used to treat conditions such as high blood pressure, angina, certain types of "cardiac arrhythmias", and migraine headaches.

2. Beta-Blockers Sometimes Used for Aggressive Behavior

It has been theorized that beta-blocking medications might help aggressive behavior by blocking the "fight" component of the "fight or flight" response within the adrenergic nervous system. These medications *may* be the treatment of choice for aggression, hostility, or rage associated with a concussion or with acute encephalitis.

Unfortunately, at this time, there is no method to predict which people will benefit from beta-blockers. When these medications are used on a trial basis to determine if the person is helped, the facility should ensure that **Specific Safety Precautions** unique to aggressive behavior and the use of beta-blockers are taken. These **Specific Safety Precautions** are to protect the person from serious adverse drug reactions and from any potential decrease in the person's capabilities to think clearly and function effectively. Examples of beta-blockers are shown in the box below.

Beta-Blockers Sometimes Used for Aggressive Behaviors

Generic Name:	nadolol	pindolol	propranolol
Trade Name:	Corgard	Visken	Inderal

3. Specific Safety Precautions for Beta-Blockers Sometimes Used for Aggressive Behavior

Apply the **General Safety Precautions** listed in **Part I** and these **Specific Safety Precautions** unique to beta-blockers used for aggressive behavior.

1. **Rule Out Other Reasons for Aggressive Behavior**
2. **Begin with a Low Dose of the Beta-Blocker**
3. **Screen for Higher Doses of the Beta-Blocker**
4. **Ensure a Sufficient Trial Period for the Beta-Blocker**
5. **Monitor for Adverse Drug Reactions (ADRs) from the Beta-Blocker**

D. Beta-Blockers Sometimes Used for Aggressive Behavior

1. Rule Out Other Reasons for Aggressive Behavior

How can a surveyor determine if the beta-blocker is used for aggressive behavior or for conditions that are approved by the Food and Drug Administration (FDA)?

When beta-blockers are used for reasons that are approved uses by the Food and Drug Administration (FDA), the facility should have substantial information in the clinical record to demonstrate that one or more of the conditions shown in the box at right is present in the person being treated.

BETA - BLOCKERS

FDA APPROVED USES

Propranolol for each of the following conditions and **Nadolol** for 1 and 5 only:

1. Angina Pectoris
2. Cardiac Arrhythmias
3. Essential Tremor
4. Glaucoma
5. High Blood Pressure
6. Hypertrophic Subaortic Stenosis
7. Migraine Prophylaxis
8. Myocardial Infarction
9. Pheochromocytoma
10. Thyrotoxicosis

ACCEPTED USES

1. Aggressive Behavior
2. Neuroleptic Induced Akathisia (See Definitions.)

If the facility is using one of these medications for a use that is approved by the FDA **and** the dose is proper **and** the facility monitors for adverse drug reactions (ADRs), it is difficult to conclude that the use of the drug is unnecessary. If the facility has substantial information to demonstrate these conditions are met and the patient is not experiencing any ADRs, it is likely that the use of the drug is appropriate. (For a list of these ADRs, refer to **Specific Safety Precaution # 5. "Monitor for Adverse Drug Reactions (ADRs) from the Beta-Blocker"** on pages 64 and 65.) However, if an FDA approved reason for use is not present, then the information in the boxes on the following page will help the surveyor determine if these **Specific Safety Precautions** should be applied to the use of the beta-blocker.

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an accurate and comprehensive functional assessment.
42 CFR 483.440(c)(4) requiring an individual program plan . . . to meet the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh the potentially harmful effects of the drug.

D. Beta-Blockers Sometimes Used for Aggressive Behavior

Is the Beta-Blocker Used for Aggressive Behavior?

If there is no data in the clinical record to support the use of the drug for the FDA approved "indications for use",
and
there are indications that the person has exhibited aggressive behavior;

then presume the use of the drug is for aggressive behavior
and
apply all **General Safety Precautions in Part I**
and
the **Specific Safety Precautions** unique to beta-blockers.

Is the Beta-Blocker Used for Neuroleptic Induced Akathisia?

If there is no data in the clinical record to support the use of the drug for the FDA approved "indications for use",
and
there is information to show that the person is currently taking an antipsychotic medication,
and
the clinical record demonstrates that the person has or has had neuroleptic induced akathisia;

then presume the use of the drug is for neuroleptic induced akathisia
and
only apply the **Specific Safety Precautions** unique to beta-blockers.

2. Begin with a Low Dose of the Beta-Blocker

The facility has substantial information to demonstrate that it initiated a low dose and then, if necessary, gradually increased the dose to achieve the desired response. Refer to the box below.

LOW BEGINNING DOSES for CERTAIN BETA - BLOCKERS

Beta - Blocker	Range for Initial Daily Dose*	Increase by	Time frame
Nadolol	10 mg to 30 mg	10 mg to 30 mg	every 4 to 5 days
Pindolol	10 mg	10 mg	every 4 to 5 days
Propranolol	20 mg to 60 mg	20 mg to 60 mg	every 4 to 5 days

* In people for whom there is concern about hypotension or bradycardia the lowest initial dose should be used.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring lowest possible dose.

3. Screen for Higher Doses of the Beta-Blockers

The facility has substantial information to demonstrate that it uses dose levels associated with optimal response and/or attempts to adjust dose levels to avoid intolerable adverse drug reactions such as low heart rate and/or low blood pressure. Refer to box below.

SCREEN FOR HIGHER DOSES OF CERTAIN BETA - BLOCKERS

These dose levels are given to establish a point at which higher doses should be explained. If the person is prescribed a higher dose than shown, the facility should explain the specific clinical circumstances requiring the higher dose.

GENERIC	TRADE	DAILY ORAL DOSE* (in milligrams) Adults	Children
Nadolol	Corgard	100	75
Pindolol	Visken	60	45
Propranolol	Inderal	200	150

* **These are not maximum doses!** When higher doses are prescribed, the facility should explain in the clinical record the unique circumstances which require the higher dose.

Appropriate clinical doses vary greatly depending on the individual signs or symptoms, age, weight, and other factors. Doses lower than these are often adequate to achieve the desired outcome for the person.

REGULATORY BASIS:
42 CFR 483.450(e)(1) requiring the lowest possible dose.

4. Ensure a Sufficient Trial Period for the Beta-Blocker

The facility has substantial information to show that it uses the beta-blocker in optimal doses for a **minimum of six weeks** before it determines that the beta-blocker is not achieving the desired outcome for the person's aggressive behaviors. The facility may use the beta-blocker for a shorter trial period if the person experiences adverse drug reactions or other justification is provided.

REGULATORY BASIS:
42 CFR 483.450(e)(2) requiring that medications only be used when an integral part of an individual program plan directed specifically toward reduction or elimination of behaviors for which the medications are used.

5. Monitor for Adverse Drug Reactions (ADRs) from the Beta-Blocker

The facility has substantial information to show that it is monitors the person for :

a. postural hypotension (low blood pressure upon standing) by comparing if possible, standing and sitting/lying blood pressure;
b. signs and symptoms of postural hypotension such as dizziness upon standing, lightheadness upon standing, transient unsteady gait upon standing, and unexplained falls; and
c. bradycardia (low heart rate).

This should occur:

a. every 7 to 14 days after initiating therapy for at least the first three months or until the dose and cardiovascular status are stable, whichever is longer;
b. every 7 to 14 days after any subsequent dose increase for at least one month or until the dose and cardiovascular status are stable, whichever is longer;
c. thereafter, as clinically indicated but at least once every three to six months if the dose and cardiovascular status are stable.

Significant ADRs from Beta-Blockers are shown in the box below.

Adverse Drug Reactions (ADRs) from Beta-Blockers

Bradycardia (Slow Heart Rate)	Hallucinations
Depression	Hypotension (Low Blood Pressure)
Disorientation	Lethargy

Exacerbation (Worsening) of Chronic Obstructive Pulmonary Disease (COPD)

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status."

E. Antidepressant Medications

1. What Is Depression? 68

2. How Can Depression Be Treated? 68

3. Antidepressant Medications 70

4. Specific Safety Precautions for Antidepressant Medications 70

1. What Is Depression?

The term "depression" can be used in different ways. Sometimes it is used to describe "feeling down" or "feeling blue". Other times it is used to describe more objectively and medically defined conditions such as depressive disorder, mixed depressive episode, and major depressive episode. As used in this category, Medications for Depression, the term "depression" refers to a Major Depressive Episode.

Antidepressant medications are used for Major Depressive Episodes as defined by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). The DSM-IV defines a Major Depressive Episode by the criteria listed on page 69, titled "**Criteria for Major Depressive Episode**".

2. How Can Depression Be Treated?

Treatment of depression may involve different therapies: medication, psychotherapy, counseling, or electroconvulsive therapy (ECT). These may be used alone or in combination. For example, in mild cases of depression, psychotherapy or counseling alone may suffice. Individual response is usually better when psychotherapy or counseling is used in combination with medication; however, non-medication therapy alone is used for people who refuse medication, do not respond to medication, cannot tolerate its adverse drug reactions, or for whom it is contraindicated.

■ Criteria for Major Depressive Episode

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

(1) depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
Note: In children and adolescents, can be irritable mood.

(2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or others' observations)

(3) significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.
Note: In children, consider failure to make expected weight gains.

(4) insomnia or hypersomnia nearly every day

(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)

(6) fatigue or loss of energy nearly every day

(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)

(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)

(9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B. The symptoms do not meet criteria for a Mixed Episode.

C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological drug effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

Adopted from page 327 of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV);
Fourth Edition with permission of the American Psychiatric Association.

3. Antidepressant Medications

Antidepressant medications work by inhibiting the reuptake of certain neurotransmitters and increasing their levels in the nerve synapse. Although these increased levels help to relieve depression, the resulting increased concentration of neurotransmitters can also cause an adverse drug reaction (ADR). Some ADRs are psychomotor excitation, dry mouth, blurred vision, drowsiness, and/or orthostatic hypotension. These and other ADRs are discussed more fully in this section. Newer antidepressant medications such as the Selective Serotonin Reuptake Inhibitors (SSRIs) usually have fewer ADRs; however, the SSRIs can also have ADRs such as restlessness and insomnia. The chart on page 73, "**Usual Dosage, Mechanism of Action, and Adverse Drug Reactions of Antidepressants**", lists the most commonly used antidepressant medications with their generic, brand names, and individual ADRs. This chart also shows each antidepressant medication's relative capability to inhibit reuptake of norepinephrine and serotonin and thereby relieve depression.

4. Specific Safety Precautions for Antidepressant Medications

Apply the **General Specific Safety Precautions** listed in **Part I** and the following **Specific Safety Precautions** unique to medications for depression:

1. **Rule Out Other Causes for the Depression**

2. **Monitor For Adverse Drug Reactions from Antidepressant Medications**

3. **Be Alert to Symptoms of Psychomotor Excitation**

1. Rule Out Other Causes for the Depression

When antidepressant medications are used to treat depression the facility has substantial information that it considered and ruled out other causes for depression before it institutes medication therapy. Among these other causes may be the use of certain medications which can cause or aggravate depression. Refer to the list in the box below.

AVOID THESE:
Medications That Cause or Aggravate Depression

Generic Name	Trade Name
alcohol (ethanol)	Many Brands, Beer, Liquor, Wines, etc.
amphetamines (withdrawal)	Dexedrine
anabolic steriods	Danocrine, Halotestin, Oreton-Methyl
baclofen	Atrofen, Lioresal
barbiturates	See page 30 for list.
benzodiazepines	See pages 19 and 28 for lists.
beta-blockers	See page 58 for list.
chloral hydrate	Many Brands, e.g. Noctec
cimetidine	Tagamet
clonidine	Catapres
corticosteriods	Cortisone, Hydrocortisone, Cortef, Decadron, Medrol, Aristocort,etc.
digoxin	Lanoxin
diltiazem	Cardizem
disulfiram	Antabuse
levodopa	Dopar, Laradop
levodopa/carbidopa	Sinemet
meprobamate	Equanil, Miltown
methyldopa	Aldomet
methylphenidate (withdrawal)	Ritalin
nifedipine	Procardia, Adalat
oral contraceptives	Loestrin, Ortho-Novum, Demulen, Norlestrin, Norinyl, others.
pemoline (withdrawal)	Cylert
phenylpropanolamine (withdrawal)	Dexatrim, Acutrim, and many cold and cough preparations
prazosin	Minipress
procainamide	Pronestyl
ranitidine	Zantac
reserpine	Serpasil

REGULATORY BASIS:
42 CFR 483.440(c)(3) requiring an accurate and comprehensive functional assessment.
42 CFR 483.440(c)(4) requiring an individual program plan . . . to meet the client's needs.
42 CFR 483.450(e)(3) requiring that harmful effects of behavior clearly outweigh the potentially harmful effects of the drug.

2. Monitor For Adverse Drug Reactions (ADRs) from Antidepressant Medications

The facility has substantial information to demonstrate that it adequately monitored for adverse drug reactions (ADRs). If an ADR occurs, the facility has documentation showing why the ADR did not significantly impair the person's functional status and why the medication was not changed, discontinued, or decreased in dose.

The "**Usual Dosage, Mechanism of Action, and Adverse Drug Reactions of Antidepressants**" on the next page lists commonly used antidepressant medications and their ADRs. The symptoms and indications from an ADR can occur alone or in combination with other ADRs. The ADRs listed in this chart are defined in "**Definitions**".

REGULATORY BASIS:
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

Table 5

Usual Dosage, Mechanism of Action, and Adverse Effects of Antidepressants

Drug or Drug Class	Brand Name	Usual Dosage (mg/day)	Reuptake Inhibition		Adverse Effects					
			N	S	ACH	Drowsiness	Orthostatic hypotension	Cardiac arrhythmias	GI distress	Weight gain
First-Generation Antidepressants										
Tricyclic Antidepressants										
Amitriptyline	Elavil, Endep	100-300	Moderate	High	4+	4+	4+	3+	0	4+
Clomipramine†	Anafranil	100-250	Moderate	High	4+	4+	2+	3+	1+	4+
Desipramine	Norpramin, Pertofrane	100-300	High	Low	1+	2+	2+	2+	0	1+
Doxepin	Adapin, Sinequan	100-300	Low	Moderate	3+	4+	2+	2+	0	4+
Imipramine	Janimine, Tofranil	100-300	Moderate	Moderate	3+	3+	4+	3+	1+	4+
Nortriptyline	Aventyl, Pamelor	50-200	Moderate	Low	2+	2+	1+	2+	0	1+
Protriptyline	Vivactil	15-60	Moderate	Low	2+	1+	2+	3+	0	0
Trimipramine	Surmontil	100-300	Low	Low	4+	4+	3+	3+	0	4+
Monoamine Oxidase Inhibitors										
Phenelzine	Nardil	15-90	—	—	2+	2+	2+	1+	1+	3+
Tranylcypromine	Parnate	10-40	—	—	2+	1+	2+	1+	1+	2+
Second-Generation Antidepressants										
Older Second-Generation Antidepressants										
Amoxapine	Asendin	100-400	Moderate	Low	2+	2+	2+	2+	0	2+
Maprotiline	Ludiomil	100-225	Moderate	Low	2+	3+	2+	2+	0	2+
Trazodone	Desyrel	150-500	Very low	Moderate	0	4+	3+	1+	1+	2+
Newer Second-Generation Antidepressants										
Bupropion	Wellbutrin	300-450**	Very low***	Very low***	0	0	0	1+	1+	0
Third-Generation Antidepressants										
Selective Serotonin Reuptake Inhibitors										
Fluoxetine	Prozac	10-40	Very low	High	0	0	0	0	3+*	0
Paroxetine	Paxil	20-50	Very low	Very high	1+	1+	0	0	3+*	1+
Sertraline	Zoloft	50-150	Very low	Very high	0	0	0	0	3+*	0
Serotonin/Norepinephrine Reuptake Inhibitor										
Venlafaxine‡	Effexor	75-375	Very high	Very high	1+	1+	0	1+	3+*	0

Key:
- N — norepinephrine
- S — serotonin
- ACH — anticholinergic effects (dry mouth, blurred vision, urinary retention, constipation)
- * — Nausea is usually mild and transient.
- ** — Not to exceed 150 mg/dose to minimize seizure risk.
- *** — Norepinephrine and serotonin reuptake inhibition is minimal, but inibits dopamine reuptake.
- † — Not approved by FDA for depression.
- ‡ — Comparative studies evaluating the adverse effects of venlafaxine in relation to other antidepressants have not been performed.
- 0 — Absent or rare
- 1+
- 2+ — In between
- 3+
- 4+ — Relatively common

Two New Anti-Depressants Recently Approved by FDA

Fluvoxamine . . . . Luvox
Nefazodone . . . . .Serzone

Adapted from page 7 of the A.Ph.A. Special Report, "Therapeutic Options in the Treatment of Depression" with permission of the American Pharmaceutical Association (A.Ph.A.).

3. Be Alert to Symptoms of Psychomotor Excitation

The facility has substantial information to demonstrate that it adequately monitors for psychomotor excitation. If this adverse drug reaction(ADR) occurs, the facility has documentation showing why the psychomotor excitation is not significantly impairing the person's functional status or why the medication was not changed, discontinued, or decreased in dose.

Psychomotor Excitation is a significant ADR not listed in the "**Usual Dosage, Mechanism of Action, and Adverse Drug Reactions of Antidepressants**" on the previous page. When antidepressant medication is prescribed, especially in the newer Selective Serotonin Reuptake Inhibitors (SSRIs), one or more of the following symptoms can indicate psychomotor excitation:

Agitation	Confusion	"Pins and Needles" in Extremities
Anxiety	Irritability	Restlessness
	Jitters	

Why Identifying Psychomotor Excitation Is Critical . . . .

IF psychomotor excitation is **not** correctly identified
and
is mistaken for behavioral or psychiatric signs or symptoms,

THEN additional psychopharmacological medication
could be inappropriately prescribed.

Note: Signs or symptoms resembling ADRs may exist as a part of a person's developmental disability. After starting medication, the facility and the surveyor should be alert to a medication exacerbating (worsening) an existing sign or symptom.

REGULATORY BASIS:
42 CFR 483.420(a)(6) requiring that the facility "ensure that clients are free from unnecessary drugs . . . and are provided active treatment to reduce dependency on drugs . . . ."
42 CFR 483.440(a)(1)(ii) requiring that active treatment be directed toward "the prevention or deceleration of regression, or loss of current optimal functional status."
42 CFR 483.450(e)(4)(i) requiring close monitoring of drug therapy.

Definitions

A

Adverse Drug Reactions (ADRs): secondary effects of a drug that are usually undesirable and different from the therapeutic effect of the drug. ADRs include a wide range of functional, structural, and biochemical effects which are not the intended effects of the drug. Also referred to as adverse effects, treatment emergent effects, or side effects. Formal definitions stress any noxious, unintended, and undesired effect of a drug which is observed in doses and usually administered in human beings. Technically, ADRs have several categories, the others being adverse effects, hypersensitivity, idiosyncracity, toxic reactions, and adverse drug interactions.

Adverse Drug Reaction (ADR) Monitoring: An organized system to periodically check the individual for medication ADRs using an accepted methodology which includes: (1) directly assessing (examining) the individual for signs or symptoms using a standardized assessment instrument such as a published rating scale or a checklist constructed from standard pharmaceutical or medical references, (2) conducting professionally recommended physiological and laboratory assessments, and (3) reviewing the drug regimen for potential and more probable ADRs. "Organized system" refers to some coordinated procedure to conduct, review, record, and act on assessment information.

Affective Disorder: a disorder of the emotional feeling, tone, and mood attached to a thought, including its external manifestations.

AIMS: short for Abnormal Involuntary Movement Scale, a standardized rating scale used to assess a person for tardive dyskinesia.

Akathisia: the inability to sit still. The resident with this disorder is driven to constant movement, including pacing, rocking or fidgeting. Akathisia also may include subjective complaints such as, "I feel like jumping out of my skin". See **Extrapyramidal Adverse Drug Reactions (ADRs).**

Amnesia: a disturbance in the memory of information stored in long-term memory. In contrast to short-term memory, manifested by total or partial inability to recall past experiences.

Angina Pectoris: a severe constricting pain in the chest area.

Antecedent Analysis: Systematic review of possible variables which might be responsible for or contributing to the onset of a behavior, sign or symptom. Antecedent variables generally fall under categories such as: (1) time and place, (2) immediate, and (3) distant. Time and place includes the time of day, days of the week, and physical location. Immediate antecedents include the activity at the time, people present, social and interpersonal events or statements, covert activity such as what the person may have been thinking or imagining (generally obtained by questioning the person or listening carefully to self-talk), and affect or emotion such as frowns, muscle tension, etc. Distant antecedents include non-immediate events such as a stress event such as the person's family member not keeping an appointment the day before, hunger due to missing a meal, discomfort from an illness or medical condition, etc.

Anticholinergic (ACH) Adverse Drug Reactions: are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. (Antipsychotic medications themselves, as well as many antidepressant medications, have ACH adverse drug reactions.)

Anticholinergic Medication: Medications such as benztropine (Cogentin), amantadine (Symmetrel), biperiden (Akineton), and trihexyphenidyl (Artane) used to treat extrapyramidal ADRs of antipsychotic medication.

Antipsychotic Medication: Medications such as thioridazine (Mellaril), chlorpromazine (Thorazine), and haloperidol (Haldol) which are typically prescribed for schizophrenia and other psychotic disorders. Also referred to as **neuroleptics** or **major tranquilizers**.

Athetosis: a constant succession of slow, writhing, involuntary movements of flexion, extension, pronation and supination of fingers, and hands, and, sometimes, toes and feet.

B

Backward Chain: A chain is a sequence of behaviors that occurs in a fixed order. **A backward chain** teaches a behavior, skill, or activity in a step by step sequence starting with the last step or action and working backward to the previous step after the step is learned. An example is learning the route from one's room to the bathroom. The person is taken to the bathroom several times on the route which has been broken down into 9 parts. The person is first taught to reliably travel the last 10 feet; the person next learns to reliably make the right hand turn before the last 10 feet plus travel the last 10 feet; etc.

Baseline: A period of time a behavior is measured to establish how often it occurs. The effectiveness of a subsequent intervention (or change in existing intervention) is evaluated by comparing it to the baseline period.

Behavioral Symptoms: discrete symptoms of behavior such as hitting, pinching, biting, crying, pacing, wandering, rocking, fidgeting which may be indicative of a medical or psychiatric condition, or due to an environmental or psychosocial stressor.

Bradycardia: slowness of the heartbeat, usually defined as a rate under 60 beats per minute.

C

Cardiac Arrhythmias: a fast, slow or irregular heart beat.

Cardiac Ischemia: a condition in which the heart muscle is deprived of oxygen as a result of mechanical obstruction (mainly arterial narrowing). Cardiac ischemia usually results in severe pain in the chest know as angina pectoris.

Clinically Contraindicated means that the facility

a. provides a description of previous gradual dose reduction failures **or**
b. fully supports why the continued use of the drug and the dose of the drug is clinically appropriate and not clinically contraindicated as demonstrated by the following four elements:
   1. **Symptomatology** is a thorough description of individual symptoms and not simply a diagnostic label or a diagnostic code.
   2. **Differential Diagnosis** is a discussion of the differential medical symptoms, including psychiatric symptoms. For example, why is the person's aggression part of a psychosis and not the result of psychosocial stressors, or pain?
   3. **Choice of Treatment** is a description of the reasoning for the choice of a particular treatment or treatments, and
   4. **Dose Level** is a discussion of why the present dose is necessary to manage the person's symptoms.

Cognitive Impairment: the impairment of a person's ability to perceive, recognize, conceive, judge, sense, reason, and imagine. Also, the loss of a person's ability to acquire knowledge.

Convulsions: a violent spasm or series of jerkings of the face, trunk, or extremeties.

D

Data Collection Methods: See **Duration Recording, Frequency Count, Interval Recording, Rating Scales, and Time Sample.**

DISCUS: Short for the Dyskinesia Identification System Condensed User Scale, a standardized rating scale used to to assess a person for tardive dyskinesia.

Drowsiness: a state of impaired awareness associated with a desire or inclination to sleep.

Duration Recording: A measurement method which records the length of time a target behavior or symptom occurs.

Dystonia: This disorder is marked by holding of the neck or trunk in a rigid, unnatural posture. Usually the head is either hyper extended or turned to the side. The condition is painful and prompt treatment with an Antiparkinson medication can be helpful. See **Extrapyramidal Adverse Drug Reactions.**

E

ECT: See **Electroconvulsive Therapy**.

Electroconvulsive Therapy: a form of treatment of mental disorders in which convulsions (seizures) are produced by the passage of an electric current through the brain.

Electro-Shock Therapy: See **Electroconvulsive Therapy**.

Epilepsy: Epilepsy is a periodic recurrence of seizures with or without convulsions. A single seizure does not constitute a diagnosis of epilepsy. Epilepsy is a group of syndromes that are further classified by type of seizure, presence or absence of convulsions, and maintenance or loss of consciousness.

Essential Tremor: (also known as Familial Tremor or Senile Tremor)-----an exaggeration of normal, alternating muscle contractions, resulting in a shaking movement in the hands, head, or face, or all three.

Extrapyramidal Adverse Drug Reactions (ADRs): are usually manifested by movement disorders that include Dystonia, Akathisia, and Parkinsonism. These neurological adverse drug reactions are associated with antipsychotic medication and may occur shortly after beginning medication or increasing its dose.

F

Facility: refers to Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) which are also called facilities for persons with developmental disabilities.

Fading: The process of gradually removing extra cues or prompts such as additional instructions or physical guidance. Initially, newly learned behavior or behavior being learned is helped by extra prompts or cues. However, it is important in most situations to gradually remove the extra prompts as the person learns to attend to a situation's natural cues or prompts.

Familial Tremor: See **Essential Tremor**.

Forward Chain: A chain is a sequence of behaviors that occurs in a fixed order. A **forward chain** teaches a behavior, skill, or activity in a step by step sequence starting with the first step or action and proceeding forward to the next step after the step is learned. An example is learning to tie shoelaces. The person is first taught to reliably hold the two ends of the shoelaces; the person next learns to reliably hold the two ends and cross them over; etc.

Frequency Count: A measurement method in which every instance or episode of a target behavior or symptom is recorded. Also called **event recording**. If the total number of incidents or episodes for a period of time is divided by that period of time, the **rate** of the behavior or symptom is computed for that selected period of time.

Functional Loss: or Loss of Functional Status or is defined as a **measurable loss** of a person's previously possessed ability to function in one or more of the following ways:

- Activities of Daily Living, for example, locomotion, bathing, dressing, eating, etc.
- Cognition or Thinking, especially in memory and orientation
- Communication
- Continence, bladder or bowel
- Motivation and Interest in Preferred Activities

G

Gastro-Intestinal (G.I.) Distress: is indicated by stomach or abdominal pain or discomfort, nausea, vomiting or diarrhea.

Glaucoma: an eye disease that results in defects in the field of vision. Atrophy (shrinking) of the optic nerve, excavation, and increased intraocular pressure characterize glaucoma.

H

Hallucinations: false or distorted strong subjective perception of an object or event, with an overwhelming sense or their reality, when no such object or event exists. Visual and auditory hallucinations involve seeing or hearing things that are not there.

Hypertrophic Subaortic Stenosis: obstruction of blood flow from the left ventricle (chamber) of the heart due to the hypertrophy (enlargement) of the ventricular septum (thin wall of tissue between the two ventricles).

Hypnotic: sleep inducing.

Hypomania: a mild degree of mania.

Hypotension: systolic blood pressure is less than 90 millimeters of mercury.

I

Interval Recording: A measurement method in which a period of time is divided into equal segments ("intervals"), and the target behavior or symptom is recorded as occurring or not occurring at any time during each interval. For example, a 24 hour day may be divided into 48 one-half hour intervals. The number of intervals in which a behavior or symptom occurs is divided by the total number of possible intervals to yield a **percentage rate.**

L

Lethargy / Sedation: See Drowsiness.

M

Mania: an emotional disorder characterized by euphoria, increased psychomotor activity, rapid speech, flight of ideas, decreased need for sleep, distractibility, grandiosity, and poor judgement; usually occurs in bipolar disorder.

Migraine Prophylaxis: the prevention of migraine headache which is a symptom complex occurring periodically and characterized by pain in the head (usually on one side), vertigo, nausea, and vomiting, photophobia, and **scintillating appearances** of light.

Myocardial Infarction: an area of necrosis (death) of heart muscle resulting from a sudden insufficiency of arterial blood flow (usually in a coronary artery).

N

Nerve Synapse: the functional membrane--to--membrane contact of the nerve cell with another nerve cell.

Neurotransmitter: any special chemical agent (such as dopamine, epinephrine, histamine, norepinephrine, or serotonin.) which is released by one nerve cell, upon excitation, and crosses to another nerve cell to cause stimulation or inhabitation of that cell.

P

Panic Disorder: a **discrete** period of intense fear or discomfort, in which four (or more) symptoms (such as: sweating, rapid heart rate, trembling or shaking, shortness of breath, choking feeling, chest pain or discomfort, nausea, dizziness) develop abruptly and reach a peak within ten minutes.

Parkinsonism: This condition may involve any combination of tremors, postural unsteadiness, lack of or slowness of movement (akinesia), cogwheel rigidity, expressionless face, drooling, infrequent blinking, shuffling gait, decreased arm swing, and rigidity of muscles in the limbs, neck or trunk. Although the most common is pill-rolling or alternating tremor of the hands, other kinds of tremors are occasionally seen. Occasionally, a resident with Parkinsonism will have no tremor, only rigidity and shuffling gait. See **Extrapyramidal Adverse Drug Reactions (ADRs).**

Pheochromocytoma: a tumor, usually benign, derived from cells of adrenal gland tissue and characterized by the secretion of catecholamine (such as adrenaline(epinephrine), norepinephrine, etc.) resulting in high blood pressure which may be sudden in onset and associated with attacks of palpitation, headache, nausea, anxiety, paleness of the skin, and sweating.

Polypharmacy: the use of more than one medication at the same time except for brief periods when changing from one medication to another. There are two types of polypharmacy:

intraclass - the use of two or more medications from the same class (e.g. haloperidol and thioridazine). While a rare exception may occur, this is frowned upon in the literature. It is also referred to as **duplicate therapy**.

interclass - is the use of two or more medications from different classes. Since psychiatric opinion indicated the use of two ppsychotropicfrom different classes was not significantly outside normal practice, some use an interclass polypharmacy **indicator of more than two** ppsychotropicfrom different classes. While this may or may not be appropriate, depending on the individual, condition, refractory status, and co-morbid conditions, it suggests the need for **review to insure that medications are not just being added without the removal of the ineffective medication.**

Postural (Orthostatic) Hypotension: is indicated by dizziness, light-headedness, or fainting, especially when moving from a sitting position to a standing position.

Psychomotor Excitation: a significant adverse drug reaction in antidepressant medications, especially in the newer Selective Serotonin Reuptake Inhibitors, **psychomotor excitation** is manifested by one or more of the following symptoms: agitation, anxiety, confusion, irritability, jitteriness, "pins and needles" in extremities, and restlessness.

Psychopharmacological Medication: Any medication prescribed with the intent of improving or stabilizing mood, mental status, or behavior. A ssimilardefinition is any medication prescribed for psychiatric or behavior modifying purposes.
Psychopharmacological medication is typically organized into several subclasses: antianxiety, antidepressant, antipsychotic, antimania, stimulant, sedative-hypnotic, and miscellaneous. Also referred to as psychotherapeutic, psychotropic, psychoactive, or behavior modifying medications. While these terms have different nuances, for our purposes the terms are synonymous.

Q

Quality of Life: The overall pattern of how the individual is living. Includes areas such as work, recreation, interests, religion, socialization, community participation, etc.

Quality of life is important to review in relation to psychotropic medication because a specific target behavior or condition may be eliminated, but the individual does not do anything else due to sedation or other adverse drug reactions. While quality of life is relative to the individual, the basic question is, "How is the person doing in life activities? Is it better than without the medication, a different medication, or previous dose?"

R

Rate: How often a target behavior occurs over a period of time. In simple terms, target behavior can be expressed in terms of frequency using weekly totals or monthly totals (e.g. 22 aggressions for the month of March). More formally, it can be expressed in terms of a daily average for a select period of time (e.g., 4 aggressions per day for the period of June 1 to August 15.)

Rating Scales: A measurement method in which target behaviors or symptoms are recorded on a numerical gradient based upon cumulative uncontrolled observations of daily life. **Standardized rating scales** refer to scales with established items, validity, factor groupings, and reliability for conditions such as depression (for example, the Beck's Depression Inventory). Numerical gradients vary from scale to scale, but generally start with 0 = not present and advance to 4 = severe. Some rating scales may be used daily, but others are based upon patterns over the previous week. **Nonstandardized rating scales** may be designed specific to the individual based upon the specific behaviors, symptoms, and situations involved. Two key variables to better rating scales are how well individual items and the scoring system are defined.

S

Sedation / Lethargy: See **Drowsiness**.

Senile Tremor: See **Essential Tremor**.

Seizure Disorder: See **Epilepsy**.

Shaping: The process of developing a new behavior by reinforcing or rewarding closer and closer levels (successive approximations) to the final desired behavior or skill level. Successive approximations are behaviors or responses which increasingly resemble the final behavior or skill level.

Shock Treatments: See **Electroconvulsive Therapy**.

Spasticity: a state of increased muscle tone (contraction) with exaggeration of tendon reflexes.

Specific Program Steps With Criteria Levels For Advancement or Remedial Branching: Refers to an organized plan to teach a person a skill or help a behavior. **Specific Program Steps** refer to a series of objectively defined adjustments of variables such as teaching activity, prompts, reinforcers, or actions as skills are learned or behavior improves. **Criteria Levels** are objectively defined levels which inform the instructor and person that a specific program step has either been: (1) learned and the person should advance to the next program step, or (2) not learned in a reasonable amount of time and practice and the person should drop back to the previous program step for more practice or an intermediate step between the previous and current step. **Remedial Branching** refers to a step or a series of steps (usually developed when a problem occurs) between the last successfully learned program step and the current unsuccessfully learned program step. Upon completion of the remedial branching step(s), the person returns to the problem program with increased skill to try the step again.

Status Epilepticus: a repeated seizure or a seizure prolonged for at least 30 minutes; may be convulsive (tonic-clonic), nonconvulsive (absence) or partial.

Stimulus Control: The display of a different form or frequency of a behavior in the presence of one stimulus or set of conditions, but not displayed in the presence of another stimulus or set of conditions. The behavior occurs when a certain stimulus or condition is present, but does not occur when that particular stimulus or condition is absent. Stimulus control on the applied level generally revolves around: (1) removing or changing an antecedent situation or condition which is associated with the problem behavior, and (2) teaching the person the necessary skills to recognize, deal with, or change or avoid the stimulus.

Substantial information to demonstrate: means that the facility has a valid clinical reason for using this drug as evidenced by evaluation of some, but not necessarily all, of the following: individual assessment, plan of care, reports of significant change, progress notes, laboratory reports, professional consultations, data on specifically defined target behaviors, drug orders, observation and interview with the patient, interview of the direct care staff, family, other residents, and other information. It does not simply mean that the order for the drug includes a diagnostic label.

T

Tardive Dyskinesia (TD): persistent, sometimes permanent movements induced by long-term use (generally one to two years or more) of antipsychotic medication therapy. TD consists of abnormal involuntary muscle movements such as facial grimacing, chewing, puckering, or movements of the lips such as lip smacking, and thrusting movements of the tongue. TD may dissipate over time (withdrawal TD), but can be persistent or irreversible. Although there is no consistently effective treatment, **withdrawal of the antipsychotic medication leads to eventual reversal of the symptoms over many months in about 50% of cases.**

Target Behaviors: The behavior(s) that an intervention is intended to alter or change. The efficacy of the intervention is determined by reviewing its effect on the specific behavior and quality of life indicators. A **target behavior** should be objectively defined and measured using a specific methodology such as a frequency count, time sample, or a rating scale. Synonyms for **target behavior** are: index behavior, target signs (i.e., an observable behavior), and target symptoms (i.e. verbal or subjective experience reported by the person).

Task Analysis: Refers to analyzing or breaking down a skill, task, or activity into a set of skills the person must perform in order to successfully accomplish the skill, task, or activity. A completely developed task analysis will consider and provide a description of the component behavioral skills necessary, the relationships among these components, and the function of each component in the total task. Most importantly, a true task analysis specifies in order the steps the learner will be taking when he or she is performing the task.

Time Sample: A measurement technique in which a period of time is divided into equal segments and a target behavior recorded as occurring or not occurring when the individual is observed for a short period of time at the end of each segment. For example, 16 waking hours from 6:00 am to 10:00 pm hour day may be divided into 32 one-half hour segments with the individual "spot checked" at 6:30 am, 7:00 am, 7:30 am, etc. The number of "spot checks" the behavior or symptom is observed is divided by the total number of possible observations to yield a **percentage rate.**

Thyrotoxicosis: a state produced by excessive quantities of endogenous (originating from within) or exogenous (taken into the body) thyroid hormone.

Tremor: See **Essential Tremor**.

W

Withdrawal Reaction: The temporary physiological or behavioral changes resulting from the removal of psychotropic medication. Also referred to as withdrawal symptoms or withdrawal adverse effects. Withdrawal reactions are more likely with rapid or abrupt decreases and less likely with gradually reducing the dose. However, withdrawal reactions can still occur, though usually in a milder form, for certain medications such as benzodiazepines (e.g., diazepam) and sedative-hypnotics (e.g., chloral hydrate). Signs may include diarrhea, tremors, convulsions, depression, excessive sleeping, lack of eating, and temporary target behavior increases or new maladaptive behaviors.

PART III.

REFERENCED REGULATIONS

Part III Referenced Regulations*

§483.420 Condition of Participation: Client Protections.
42 CFR 483.420(a)(6) 89

§483.440 Condition of Participation: Active treatment services.
42 CFR 483.440(a)(1)(ii) 89
42 CFR 483.440(c)(3) 90
42 CFR 483.440(c)(4) 91
42 CFR 483.440(f)(1)(I)(ii), and (iii) 92

§483.450 Condition of participation: Client behavior and facility practices.
42 CFR 483.450(b)(1)(iii) 93
42 CFR 483.450(e)(1) 94
42 CFR 483.450(e)(2) 94
42 CFR 483.450(e)(3) 94
42 CFR 483.450(e)(4)(i) 94
42 CFR 483.450(e)(4)(ii) 94

§483.460 Condition of participation: Health care services.
42 CFR 483.460(a)(3)(iii). 94

Cross Reference of Regulations and Safety Precautions 95

* The complete text of the regulations applicable to Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) is found in Title 42 of the Code of Federal Regulations (CFR), Part 483, Subpart I, Sections 400 through 480.

§483.420 Condition of Participation: Client Protections.

(a) Standard: Protection of clients' rights. The facility must ensure the rights of all clients. Therefore the facility must --- . . .

(6) Ensure that clients are from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints; . . . .

§483.440 Condition of Participation: Active treatment services.

(a) Standard: Active treatment.

(1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward--

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

§483.440 . . . Active treatment services . . . continued

(c) Standard: Individual program plan.

(1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to- -

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless the participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must- -

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's needs for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

§483.440 . . . Active treatment services . . . continued

(c) Standard: Individual program plan . . . continued

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must- -

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

§483.440 . . . Active treatment services . . . continued

(f) Standard: Program monitoring and change.

(1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client-

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made or;

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed; and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

§483.450 Condition of participation: Client behavior and facility practices.

(b) Standard: Management of inappropriate client behavior.

(1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must- -

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:
- (A) The use of time-out rooms;
- (B) The use of physical restraints;
- (C) The use of drugs to manage inappropriate behavior;
- (D) The application of painful or noxious stimuli;
- (E) The staff members who may authorize the use of specified interventions;
- (F) A mechanism for monitoring and controlling the use of interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with §483.440(c)(4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

§483.450 Condition of participation: Client behavior and facility practices.

(e) Standard: Drug usage.

(1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be- -

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at §483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§483.460 Condition of participation: Health care services.

(a) Standard: Physician services.

(3) The facility must provide or obtain preventive and general care as well as annual physical examinations of each client that at a minimum include the following: . . .

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed; . . . .

Cross Reference of Regulations and Safety Precautions

Regulation — **Safety Precautions (page number)**

§483.420 Client protections.

42 CFR 483.420(a)(6). 30, 31, 38, 39, 42, 43, 46, 48, 50, 52, 54, 74

§483.440 Active treatment services.

42 CFR 483.440(a)(1)(ii) 8, 65, 74
42 CFR 483.440(c)(3) 4, 5, 26, 60, 71
42 CFR 483.440(c)(4) 4, 5, 18, 26, 60, 71
42 CFR 483.440(f)(1)(i)(ii), and (iii). 8

§483.450 Client behavior and facility practices.

42 CFR 483.450(b)(1)(iii) 6, 27
42 CFR 483.450(e)(1) 7, 19, 28, 55, 62, 63
42 CFR 483.450(e)(2) 5, 7, 64
42 CFR 483.450(e)(3) 4, 5, 26, 39, 43, 60, 71
42 CFR 483.450(e)(4)(i) 7, 18, 27, 39, 40, 43, 44, 52, 53, 65, 72, 74
42 CFR 483.450(e)(4)(ii) 8, 20, 29, 32, 46, 52

§483.460 Health care services.

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