

APPENDIX B

Excerpts from Federal Regulations (OBRA) for Skilled Nursing
Facilities (SNFs) and Nursing Facilities (NFs)
Effective Date; March, 2005

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident.

F155 – §483.10(b) (4)

The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section.

Interpretive Guidelines §483.10(b)(4)

“Treatment” is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

If a resident’s refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident’s refusal of treatment does not absolve a facility from providing a resident with care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being in the context of making that refusal.

F157 – §483.10(b)(11) – Notification of changes.

- (i) A facility must immediately inform the resident; consult with the resident’s physician; and if known, notify the resident’s legal representative or an interested family member when there is--
 - (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
 - (B) A significant change in the resident’s physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
 - (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
 - (D) A decision to transfer or discharge the resident from the facility as specified in §483.12(a).

Interpretive Guidelines §483.10(b)(11)

For purposes of §483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset, or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment “significantly” means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

In the case of a competent individual, the facility must still contact the resident’s physician and notify interested family members, if known. That is, a family that wishes

to be informed would designate a member to receive calls. Even when a resident is mentally competent, such a designated family member should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident.

The requirements at §483.10(b)(1) require the facility to inform the resident of his/her rights upon admission and during the resident's stay. This includes the resident's right to privacy (§483.10(e), F164). If, after being informed of the right to privacy, a resident specifies that he/she wishes to exercise this right and not notify family members in the event of a significant change as specified at this requirement, the facility should respect this request, which would obviate the need to notify the resident's interested family member or legal representative, if known. If a resident specifies that he/she does not wish to exercise the right to privacy, then the facility is required to comply with the notice of change requirements.

In the case of a resident who is incapable of making decisions, the representative would make any decisions that have to be made, but the resident should still be told what is happening to him or her.

In the case of the death of a resident, the resident's physician is to be notified immediately in accordance with State law.

F164 – §483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

- (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;
- (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;
- (3) The resident's right to refuse release of personal and clinical records does not apply when--
 - (i) The resident is transferred to another health care institution; or
 - (ii) Record release is required by law

Interpretive Guidelines – §483.10(e) "Right to privacy"

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Personal and clinical records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated or other.

F176 – §483.10(n) Self-Administration of Drugs

An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.

Interpretive Guidelines §483.10(n)

If a resident requests to self-administer drugs, it is the responsibility of the interdisciplinary team to determine that it is safe for the resident to self-administer drugs before the resident may exercise that right. The interdisciplinary team must also determine who will be responsible (the resident or the nursing staff) for storage and documentation of the administration of drugs, as well as the location of the drug administration (e.g., resident’s room, nurses’ station, or activities room). Appropriate notation of these determinations should be placed in the resident’s care plan.

The decision that a resident has the ability to self-administer medication(s) is subject to periodic re-evaluation based on change in the resident’s status. The facility may require that drugs be administered by the nurse or medication aide, if allowed by State law, until the care planning team has the opportunity to obtain information necessary to make an assessment of the resident’s ability to safely self-administer medications. If the resident chooses to self-administer drugs, this decision should be made at least by the time the care plan is completed within seven days after completion of the comprehensive assessment.

F222 – Use Tag F222 for deficiencies concerning chemical restraints.

§483.13(a) - Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.

Intent §483.13(a)

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Interpretive Guidelines §483.13(a) – Definitions of Terms

“Chemical Restraints” is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

“Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

“Convenience” is defined as any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and not in the resident’s best interest.

“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident’s right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.

F271 – §483.20(a) Admission Orders

At the time each resident is admitted, the facility must have physician orders for the resident’s immediate care.

Intent §483.20(a)

To ensure the resident receives necessary care and services.

Interpretive Guidelines §483.20(a)

“Physician orders for immediate care” are those written orders facility staff need to provide essential care to the resident, consistent with the resident’s mental and physical status upon admission. These orders should, at a minimum, include dietary, drugs (if necessary) and routine care to maintain or improve the resident’s functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.

F272 – §483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident’s functional capacity.

Intent §483.20

To provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident’s status. The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident’s physician, family members, or outside consultants and review of the resident’s record.

§483.20(b) Comprehensive Assessments

§483.20(b)(1) Resident Assessment Instrument

A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State.

§483.20(b) Intent

To ensure that the RAI is used in conducting comprehensive assessments as part of an ongoing process through which the facility identifies the resident's functional capacity and health status.

§483.20(b) Guidelines

The information required in §483.20(b)(i-xvi) is incorporated into the MDS, which forms the core of each State's approved RAI. Additional assessment information is also gathered using triggered RAPs.

Each facility must use its State-specified RAI (which includes both the MDS and utilization guidelines which include the RAPs) to assess newly admitted residents, conduct an annual reassessment and assess those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or RAPs. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. Furthermore:

(xiv) Medications

"Medications" (xiv) corresponds to MDS v. 2.0, section O, and section U, if completed.

"Medications" refers to all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information need not appear in the assessment. However, it must be in the resident's clinical record and included in the care plan.

F281 – §483.20(k)(3)

The services provided or arranged by the facility must -

- (i) Meet professional standards of quality.

Intent §483.20(k)(3)(i)

The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

Interpretive Guidelines §483.20(k)(3)(i)

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards

regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.
- Clinical practice guidelines published by the Agency of Health Care Policy and Research.
- Current professional journal articles.

F329 – §483.25(I) Unnecessary Drugs

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

- (i) In excessive dose (including duplicate therapy); or
- (ii) For excessive duration; or
- (iii) Without adequate monitoring; or
- (iv) Without adequate indications for its use; or
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (vi) Any combinations of the reasons above.

It is important to note that these regulations and interpretive guidelines are not meant to cast a negative light on the use of psychopharmacological drugs in long term care facilities. The use of psychopharmacological drugs can be therapeutic and enabling for residents suffering from mental illnesses such as schizophrenia or depression. The goal of these regulations and guidelines is to stimulate appropriate differential diagnosis of "behavioral symptoms" so the underlying **cause** of the symptoms is recognized and treated appropriately. This treatment may include the use of environmental and/or behavioral therapy, as well as, psychopharmacological drugs. The goal of these regulations is also to **prevent** the use of psychopharmacological drugs when the "behavioral symptom" is caused by conditions such as:

An excellent differential diagnostic process for behavioral symptoms is described in the RAP on Behavior Problems (soon to be known as behavioral symptoms). Also, a number of very practical manuals are now available that teach nursing personnel how to assess and provide individualized care for behavioral symptoms, which leads to the avoidance of physical restraints, and unnecessary drugs. These manuals include, but are not limited to, the following list:

1. "Managing Behavior Problems in Nursing Home Residents"
Department of Preventive Medicine
Vanderbilt University School of Medicine
2. "Retrain, Don't Restrain"
American Association of Homes and Services for the Aging, or
The American Health Care Association

3. “Innovations in Restraint Reduction”
American Health Care Association
4. “Avoiding Physical Restraint Use: New Standards in Care,”
National Citizens’ Coalition for Nursing Home Reform
5. “Avoiding Drugs Used as Chemical Restraints: New Standards in Care”
National Citizens’ Coalition for Nursing Home Reform

Interpretive Guidelines **§483.25(l)(1)**

A. Long-Acting Benzodiazepine Drugs

The following long-acting benzodiazepine drugs should not be used in residents unless an attempt with a shorter-acting drug (i.e., those listed under B. Benzodiazepine or Other Anxiolytic/Sedative Drugs, and under C. Drugs Used for Sleep Induction) has failed.

After an attempt with a shorter-acting benzodiazepine drug has failed, a long-acting benzodiazepine drug should not be used unless:

- Evidence exists that other possible reasons for the resident’s distress have been considered and ruled out. (see §483.25(l)(1)(iv);)
- Its use results in maintenance or improvement in the resident’s functional status (to evaluate functional status, (see §483.25(a) through (k)) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv));
- Daily use is less than four continuous months unless an attempt at a **gradual** dose reduction is unsuccessful (see §483.25(l)(1)(ii)); and
- Its use is less than, or equal to, the following listed total **daily** doses unless higher doses (as evidenced by the resident’s response and/or the resident’s clinical record) are necessary for the maintenance, or improvement in the resident’s functional status. (see §483.25(l)(1)(i).)

Long-Acting Benzodiazepines - Not Maximum Doses

Generic	Brand	Daily Oral Dosage
Flurazepam	(Dalmane)	15mg
Chlordiazepoxide	(Librium)	20mg
Clorazepate	(Tranxene)	15mg
Diazepam	(Valium)	5mg
Clonazepam	(Klonopin)	1.5mg
Quazepam	(Doral)	7.5mg
Halazepam	(Paxipam)	40mg

NOTES: When diazepam is used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia or seizure disorders), this guideline does not apply.
When long-acting benzodiazepine drugs are being used to withdraw residents from short-acting benzodiazepine drugs, this guideline does not apply.

When clonazepam is used in bi-polar disorders, management of tardive dyskinesia, nocturnal myoclonus or seizure disorders, this guideline does not apply.

The daily doses listed under long-acting Benzodiazepines are doses (usually administered in divided doses) for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.

“**Duplicate drug therapy**” is any drug therapy that duplicates a particular drug **effect** on the resident. For example, any two or more drugs, whether from the same drug category or not, which have a sedative effect. Duplicate drug therapy should prompt the facility to evaluate the resident for accumulation of the adverse effects.

For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated.

B. Benzodiazepine or other Anxiolytic/Sedative Drugs

Use of listed Anxiolytic/Sedative drugs for purposes other than sleep induction should only occur when:

1. Evidence exists that other possible reasons for the resident’s distress have been considered and ruled out. (see §483.25(l)(1)(iv));
2. Use results in a maintenance or improvement in the resident’s functional status, (to evaluate functional status, (see §483.25(a) through (k)) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv));
3. Daily use (at any dose) is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful. (see §483.25(l)(1)(ii));
4. Use is for one of the following indications as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or subsequent editions. (see §483.25(l)(1)(iv):)
 - a. Generalized anxiety disorder;
 - b. Organic mental syndromes (now called “delirium, dementia, and amnesic and other cognitive disorders” by DSM-IV) with associated agitated behaviors, which are quantitatively and objectively documented (see note number one) which are persistent and not due to preventable reasons and which constitute sources of distress or dysfunction to the resident or represent a danger to the resident or others;
 - c. Panic disorder;
 - d. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); and
5. Use is equal to or less than the following listed total **daily** doses, unless higher doses (as evidenced by the resident response and/or the resident’s clinical record) are necessary for the improvement or maintenance in the resident’s functional status. (see §483.25(l)(1)(i), F342.)

Short-Acting Benzodiazepines - Not Maximum Doses

Generic	Brand	Dose By Mouth
Generic	Brand	Daily Oral Dosage
Lorazepam	(Ativan)	2 mg
Oxazepam	(Serax)	30mg
Alprazolam	(Xanax)	0.75mg
Estazolam	(ProSom)	0.5mg

Other Anxiolytic And Sedative Drugs

Generic	Brand	Dose By Mouth
Diphenhydramine	(Benadryl)	50mg
Hydroxyzine	(Atarax, Vistaril)	50mg
Chloral Hydrate	(Many Brands)	750mg

NOTES

1. This documentation is often referred to as “behavioral monitoring charts” and is necessary to assist in: (a) assessing whether the resident’s behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident’s life in order to learn about potential causes (e.g., death in the family, not adhering to the resident’s customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, etc., (e) ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be know as behavioral symptoms).
2. The daily doses listed under Short-Acting Benzodiazepines are doses (usually administered in divided doses) for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and, when necessary, only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.
3. For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that a gradual dose reduction is clinically contraindicated.
4. Diphenhydramine, hydroxyzine and chloral hydrate are not necessarily drugs of choice for treatment of anxiety disorders. They are only listed here in the event of their potential use.

C. Drugs for Sleep Induction - Drugs used for sleep induction should only be used if:

- Evidence exists that other possible reasons for insomnia (e.g., depression, pain, noise, light, caffeine) have been ruled out. (see §483.25(l)(1)(iv));
- The use of a drug to induce sleep results in the maintenance or improvement of the resident’s functional status (to evaluate functional status, see §483.25(a) through (k) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv);)
- Daily use of the drug is less than ten continuous days unless an attempt at a gradual dose reduction is unsuccessful. (see §483.25(l)(1)(ii);) and
- The dose of the drug is equal or less than the following listed doses unless higher doses (as evidenced by the resident response and/or the resident’s clinical record) are necessary for maintenance or improvement in the resident's functional status. (see §483.25(l)(1)(i).)

Hypnotic Drugs - Not Maximum Doses

Generic	Brand	Dose By Mouth
Temazepam	(Restoril)	7.5mg
Triazolam	(Halcion)	0.125mg
Lorazepam	(Ativan)	1mg
Oxazepam	(Serax)	15mg
Alprazolam	(Xanax)	0.25mg
Estazolam	(ProSom)	0.5mg
Diphenhydramine	(Benadryl)	25mg
Hydroxyzine	(Atarax, Vistaril)	50mg
Chloral Hydrate	(Many Brands)	500mg
Zolpidem	(Ambien)	5mg

NOTES

1. Diminished sleep in the elderly is not necessarily pathological.
2. The doses listed are doses for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.
3. Diphenhydramine, hydroxyzine, and chloral hydrate are not necessarily drugs of choice for sleep disorders. They are listed here only in the event of their potential use.
4. For drugs in this category, a gradual dose reduction should be attempted at least three times within six months before one can conclude that a gradual dose reduction is clinically contraindicated.

D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs

The **initiation** of the following hypnotic/sedative/anxiolytic drugs should not occur in any dose for any resident. (See Notes for exceptions.) Residents currently using these drugs or residents admitted to the facility while using these drugs should receive **gradual** dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed. A gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. Newly admitted residents using these drugs may have a period of adjustment before a **gradual** dose reduction is attempted.

CAUTION: Do not encourage rapid withdrawal of these drugs. This might result in severe psychological withdrawal symptoms.

Barbiturates (Examples)

Generic	Brand
Amobarbital	(Amytal)
Butabarbital	(Butisol, others)
Pentobarbital	(Nembutal)
Secobarbital	(Seconal)
Phenobarbital	(Many Brands)
Amobarbital-Secobarbital	(Tuinal)
Barbiturates with other drugs	(e.g., Fiorinal)

Miscellaneous Hypnotic/Sedative/Anxiolytics

Generic	Brand
Glutethimide	(Doriden)
Methprylon	(Noludar)
Ethchlorvynol	(Placidyl)
Meprobamate	(Equinal, Miltown)
Paraldehyde brands	(Many brands)

1. Any sedative drug is excepted from this Guideline when used as a single dose sedative for dental or medical procedures.
2. Phenobarbital is excepted from this Guideline when used in the treatment of seizure disorders.
3. When Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs are used outside these Guidelines they may be unnecessary drugs as a result of inadequate indications for use. (see Survey Procedures and Probes.)

E. Antipsychotic Drug Dosage Levels

The following examples of antipsychotic drugs should not be used in excess of the listed doses for residents with organic mental syndromes (now called “delirium, dementia, and amnestic and other cognitive disorders” by DSM-IV) unless higher doses (as evidenced by the resident’s response or the resident’s clinical record) are necessary to maintain or improve the resident’s functional status. To evaluate functional status, (see §§483.25(a) through (k)) and MDS 2.0 sections B through P.

SCREEN FOR HIGHER DOSES OF ANTIPSYCHOTIC DRUGS

These dose levels are **NOT MAXIMUM DOSES**. These daily dose levels are given to establish a point at which higher doses should be explained. If a resident is prescribed a higher dose than shown, the facility should explain the specific clinical circumstance requiring the higher dose.

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	Brand	Dose
Chlorpromazine	(Thorazine)	75
Promazine	(Sparine)	150
Triflupromazine	(Vesprin)	20
Thioridazine	(Mellaril)	75
Mesoridazine	(Serentil)	25
Acetophenazine	(Tindal)	20
Perphenazine	(Trilafon)	8
Fluphenazine	(Prolixin, Permitil)	
Trifluoperazine	(Stelazine)	8
Chlorprothixene	(Taractan)	75
Thiothixene	(Navane)	7
Haloperidol	(Haldol)	4
Molindone	(Moban)	10
Loxapine	(Loxitane)	10
Clozapine	(Clozaril)	50
Prochlorperazine	(Compazine)	10
Risperidone	(Risperdal)	2

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	Brand	Dose
Olanzapine	(Zyprexa)	10
Quetiapine	(Seroquel)	200

1. The doses listed are **daily** doses (usually administered in divided doses) for residents with organic mental syndromes (now called “Delirium, Dementia, and Amnestic and other cognitive disorders by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it is necessary for the maintenance or improvement in the resident’s functional status.
2. The “specific conditions” for use of antipsychotic drugs are listed under the Guideline for §§483.25(1)(1) and (2).
3. The dose of prochlorperazine may be exceeded for short term (seven days) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time.
4. When antipsychotic drugs are used outside these Guidelines without valid reasons for the higher dose, they may be deemed unnecessary drugs as a result of excessive dose.

F. Monitoring for Antipsychotic Drug Side Effects

The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following:

- Tardive dyskinesia;
- Postural (orthostatic) hypotension;
- Cognitive/behavior impairment;
- Akathisia; and
- Parkinsonism.

NOTES: For a more detailed description of these side effects, see the RAP: Psychotropic Drug Use, pg. C-91, “Revised Long Term Care Resident Assessment Instrument User’s Manual,” Version 2.0, December 2002.

When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring.

G. Antidepressant Drugs

The under diagnosis and under treatment of depression in nursing homes has been documented in a Journal of the American Medical Association paper entitled “Depression and Mortality in the Nursing Home” (JAMA, February 27, 1991-vol. 265, No. 8). CMS continues to support the accurate identification and treatment of depression in nursing homes.

The following is a list of commonly used antidepressant drugs:

Antidepressant Drugs	
Generic Name	Brand Name
Amitriptyline*	(Elavil)
Amoxapine	(Asendin)
Desipramine	(Norpramin, Pertofrane)
Doxepin*	(Sinequan)
Imipramine*	(Tofranil)
Maprotiline	(Ludiomil)
Nortriptyline	(Aventyl, Pamelor)
Protriptyline	(Vivactil)
Trimipramine*	(Surmontil)
Fluoxetine	(Prozac)
Sertraline	(Zoloft)
Trazodone	(Desyrel)
Clomipramine*	(Anafranil)
Paroxetine	(Paxil)
Bupropion	(Wellbutrin)
Isocarboxazid*	(Marplan)
Phenelzine*	(Nardil)
Tranlycypromine*	(Parnate)
Venlafaxine	(Effexor)
Nefazodone	(Serzone)
Fluvoxamine	(Luvox)

- These are not necessarily drugs of choice for depression in the elderly. They are listed here only in the event of their potential use.

F330 – §483.25(1)(2)(i)

Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

Antipsychotic drugs should not be used unless the clinical record documents that the resident has one or more of the following “specific conditions”:

1. Schizophrenia;
2. Schizo-affective disorder;
3. Delusional disorder;
4. Psychotic mood disorders (including mania and depression with psychotic features);
5. Acute psychotic episodes;
6. Brief reactive psychosis;
7. Schizophreniform disorder;
8. Atypical psychosis;
9. Tourette’s disorder;
10. Huntington’s disease;
11. Organic mental syndromes (now called delirium, dementia, and amnestic and other cognitive disorders by DSM-IV) **with associated psychotic and/or agitated behaviors:**
 - a. Which have been quantitatively and objectively documented. This documentation is necessary to assist in:
 - (1) Assess whether the resident’s behavioral symptom is in need of some form of intervention,
 - (2) Determining whether the behavioral symptom is transitory or permanent,
 - (3) Relating the behavioral symptom to other events in the resident’s life in order to learn about potential causes (e.g., death in the family, not adhering to the resident’s customary daily routine),
 - (4) Ruling out environmental causes such as excessive heat, noise, overcrowding,
 - (5) Ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be known as behavioral symptoms); and
 - b. Which are persistent, and
 - c. Which are not caused by preventable reasons; and
 - d. Which are causing the resident to:
 - (1) Present a danger to himself/herself or to others, or
 - (2) **Continuously** scream, yell, or pace if these specific behaviors cause an impairment in functional capacity (to evaluate functional capacity, see §483.25 (a) through (k) and MDS 2.0 sections B through P), or
 - (3) Experience psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as dangerous behaviors or as screaming,

yelling, or pacing but which cause the resident distress or impairment in functional capacity; or

12. Short-term (7 days) symptomatic treatment of hiccups, nausea, vomiting or pruritus. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can be treated for longer periods of time.

Antipsychotics should not be used if one or more of the following is/are the **only** indication:

- Wandering;
- Poor self care;
- Restlessness;
- Impaired memory;
- Anxiety;
- Depression (without psychotic features);
- Insomnia;
- Unsociability;
- Indifference to surroundings;
- Fidgeting;
- Nervousness;
- Uncooperativeness; or
- Agitated behaviors which **do not** represent danger to the resident or others.

F331 – §483.25(l)(2)(ii)

Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

Interpretive Guidelines §483.25(l)(2)(ii)

Residents must, unless clinically contraindicated, have gradual dose reductions of the antipsychotic drug. The gradual dose reduction should be under close supervision. If the gradual dose reduction is causing an adverse effect on the resident and the gradual dose reduction is discontinued, documentation of this decision and the reasons for it should be included in the clinical record. Gradual dose reductions consist of tapering the resident's daily dose to determine if the resident's symptoms can be controlled by a lower dose or to determine if the dose can be eliminated altogether.

“Behavioral interventions” means modification of the resident's behavior or the resident's environment, including staff approaches to care, to the largest degree possible to accommodate the resident's behavioral symptoms.

“Clinically contraindicated” means that a resident **NEED NOT UNDERGO** a “gradual dose reduction” or “behavioral interventions” IF:

1. The resident has a “specific condition” (as listed under 1 through 10 on page P-185) and has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations), which have been stabilized with a maintenance dose of an antipsychotic drug without incurring significant side effects;
2. The resident has organic mental syndrome (now called “Delirium, Dementia, and Amnesic and other Cognitive Disorders” by DSM IV) and has had a gradual dose

reduction attempted TWICE in one year and that attempt resulted in the return of symptoms for which the drug was prescribed to a degree that a cessation in the gradual dose reduction, or a return to previous dose reduction was necessary; or

3. The resident's physician provides a justification why the continued use of the drug and the dose of the drug is clinically appropriate. This justification should include: (s) a diagnosis, but not simply a diagnostic label or code, but the description of symptoms, (b) a discussion of the differential psychiatric and medical diagnosis (e.g., why the resident's behavioral symptom is thought to be a result of a dementia with associated psychosis and/or agitated behaviors, and not the result of an unrecognized painful medical condition of a psychosocial or environmental stressor), (c) a description of the justification for the choice of a particular treatment, or treatments, and (d) a discussion of why the present dose is necessary to manage the symptoms of the resident. This information need not necessarily be in the physician's progress notes, but must be a part of the resident's clinical record.

F332 and F333 – §483.25(m) Medication Errors

The facility must ensure that - [F332] §483.25(m)(1); it is free of medication error rates of 5 percent or greater; and [F333] §483.25(m)(2); residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m)

Medication Error - the observed preparation or administration of drugs or biologicals which is not in accordance with:

1. Physician's orders;
2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological;
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

Significant medication error – one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or related term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a drug error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

Medication error rate - is determined by calculating the percentage of errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator is called "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses

ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

Medication error rate - a medication error rate of 5% or greater includes both significant and non-significant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written.

The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted.

Significant and Non-significant Medication Errors

Determining Significance – the relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

Resident Condition - the resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

Drug Category – if the drug is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows:

- A. Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol).
- B. Anticoagulants: warfarin (Coumadin).
- C. Antiarrhythmic: digoxin (Lanoxin).
- D. Antiasthmatics: theophylline (TheoDur).
- E. Antimanic Drugs: lithium salts (Eskalith, Lithobid).

Frequency of Error – if an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the drug category.

Examples of Significant and Non-Significant Medication Errors – some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as non-significant have also been

designated primarily on the basis of the nature of the drug. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors Detected

Omissions Examples (Drug ordered but not administered at least once):

Drug Order	Significance
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Quinidine 200mg TID	S**
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS
Nitrol Oint. one inch	S
* Not Significant	
**Significant	

Unauthorized Drug Examples (Drugs administered without a physician's order):

Drug Order	Significance
Feosol	NS
Coumadin 4mg	S
Zyloprim 100mg	NS
Tylenol 5 gr	NS
Motrin 400mg	NS

Wrong Dose Examples:

Drug Order	Administered	Significance
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Digoxin 0.125mg everyday	0.25mg	S
Amphojel 30ml QID	15ml	NS
Dilantin 125 SUSP 12ml	2ml	S

Wrong Route of Administration Examples:

Drug Order	Administered	Significance
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Drug Order	Administered	Significance
Colace Liquid 100mg BID	Capsule	NS
Mellaril Tab 10mg	Liquid Concentrate	NS*

Drug Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S
* If correct dose was given.		
** Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.		

Wrong Drug Examples:

Drug Order	Administered	Significance
Tums	Oscal	NS
Vibramycin	Vancomycin	S

Wrong Time Examples:

Drug Order	Administered	Significance
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given 3 after treatment	S

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

The following situations in drug administration may be considered medication errors:

- Failure to “Shake Well”: The failure to “shake” a drug product that is labeled “shake well.” This may lead to an under dose or over dose depending on the drug product and the elapsed time since the last “shake.” The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some drugs, for example dilantin, are more critical to achieve correct dosage delivery than others.
- Insulin Suspensions: Also included under this category is the failure to “mix” the suspension without creating air bubbles. Some individuals “roll” the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.
- Crushing Medications that should not be Crushed: Crushing tablets or capsules that the manufacturer states “do not crush.”

Exceptions to the “Do Not Crush” rule:

- If the prescriber orders a drug to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.

- If the facility can provide literature from the drug manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.
- Adequate Fluids with Medications: The administration of medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication. For example:
 - Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
 - Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces. The surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes). If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted; and
 - Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.
- Medications that Must be Taken with Food or Antacids: The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used drugs that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	Brand Name
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

- Medications Administered with Enteral Nutritional Formulas: Administering medications immediately before, immediately after, or during the administration of enteral nutritional formulas (ENFs) without achieving the following minimum objectives:
 - Check the placement of the naso-gastric or gastrostomy tube in accordance with the facility's policy on this subject. **NOTE:** If the placement of the tube is not checked, this is not a medication error; it is a failure to follow accepted professional practice and should be evaluated under Tag F281 requiring the facility to meet professional standards of quality.
 - Flush the enteral feeding tube with at least 30 ml of preferably warm water before and after medications are administered. While it is noted that some facility policies ideally adopt flushing the tube after each individual medication is given, as opposed to after the group of multiple medications is given, unless there are known compatibility problems between medicines being mixed together, a minimum of one flushing before and after giving the medications is all the surveyor need review. There may be cases where flushing with 30 ml after each single medication is given may overload an individual with fluid, raising the risk of discomfort or stress on body functions. Failure to flush, before and after, would be counted as one medication error and would be included in the calculation for medication errors exceeding 5 percent.

- o The administration of enteral nutrition formula and administration of dilantin should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of dilantin, then the surveyor should consider simultaneous administration a medication error.
- Medications Instilled into the Eye: The administration of eye drops without achieving the following critical objectives:
 - o **Eye Contact:** The eye drop, but not the dropper, must make full contact with the conjunctival sac and then be washed over the eye when the resident closes the eyelid; and
 - o **Sufficient Contact Time:** The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications can be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)
- Allowing Resident to Swallow Sublingual Tablets: If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this drug.
- Medication Administered Via Metered Dose Inhalers (MDI): The use of MDI in other than the following ways (this includes use of MDI by the resident). This is an error if the person administering the drug did not do all the following:
 - o Shake the container well;
 - o Position the inhaler in front of or in the resident's mouth. Alternatively a spacer may be used;
 - o For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used; and
 - o If more than one puff is required, (whether the same medication or a different medication) wait approximately a minute between puffs.

NOTE: If the person administering the drug follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be called a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors – If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, **BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY.** Counting a drug with a long half - life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half - life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders -- the latest recapitulation of drug orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the drug.

F385

§483.40 Physician Services

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

§483.40(a) Physician Supervision

The facility must ensure that:

- (1) The medical care of each resident is supervised by a physician; and
- (2) Another physician supervises the medical care of residents when their attending physician is unavailable.

F386

§483.40(b) Physician Visits

The physician must--

- (1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;
- (2) Write, sign, and date progress notes at each visit; and
- (3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

Intent §483.40(b)

The intent of this regulation is to have the physician take an active role in supervising the care of residents. This should not be a superficial visit, but should include an evaluation of the resident's condition and a review of and decision about the continued appropriateness of the resident's current medical regime.

F389**§483.40(d) Availability of Physicians for Emergency Care**

The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

Interpretive Guidelines §483.40(d)

If a resident's own physician is unavailable, the facility should attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility.

F425**§483.60 Pharmacy Services**

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

Interpretive Guidelines §483.60

The facility is responsible under §483.75(h) for the "timeliness of the services."

A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

F426**§483.60(a) Procedures**

A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

F427**§483.60(b) Service Consultation**

The facility must employ or obtain the services of a licensed pharmacist who--

- (1) Provides consultation on all aspects of the provision of pharmacy services in the facility;
- (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
- (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

Interpretive Guidelines §483.60(b)(2) and (3)

A record of receipt and disposition of controlled drugs does not need to be proof of use sheets. The facility can use existing documentation such as the Medication Administration Record (MAR) to accomplish this record.

Periodic reconciliations should be monthly. If they reveal shortages, the pharmacist and the director of nursing may need to initiate more frequent reconciliations. In situations in which loss of controlled drugs is evident, the facility may have to utilize proof of use sheets on all controlled drugs for all shifts. However, when the source of shortage is located and remedied, the facility may go back to periodic reconciliation by the pharmacist.

Please note that the regulation does not prohibit shortages of controlled drugs - only that a record be kept and that it be periodically reconciled. If the survey reveals that all controlled drugs are not accounted for, refer the case to the State nursing home licensure authority, or to the State Board of Pharmacy.

F428

§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

Interpretive Guidelines §483.60(c)(1)

It may be necessary to review more frequently (e.g., every week) depending on the residents' condition and the drugs they are taking.

F429

§483.60(c)(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and

Miscellaneous Drugs That Are Potentially Inappropriate in the Elderly

The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, MD. This paper was published in the "Archives of Internal Medicine," Volume 157, July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times:

1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit."
2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur."

These criteria are divided into two broad categories. Drug therapy that is classified as having “high severity” and therapy that is considered as not having “high severity.” Severity is defined as: “a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur.” The survey guidelines are located in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation.

1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with §483.25(l)(1), Unnecessary Drug (F329), and
2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with §483.60(c)(1), Drug Regimen Review Report (F429) which are located under guidance to surveyors for drug regimen review.

It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety.

List of Drug Combinations With High Potential for Less Severe Adverse Outcomes

1. Phenylbutazone (Butazolidin)

Risk: “May produce serious hematological side effects (blood disorders) and should not be used in elderly patients.”

Blood disorders include bone marrow depression, aplastic anemia, agranulocytosis, leukopenia, pancytopenia, thrombocytopenia, macrocytic or megaloblastic anemia.

2. Trimethobenzamide (Tigan)

Risk: “Trimethobenzamide is one of the least effective antiemetics, yet it can cause extrapyramidal side effects.”

Extrapyramidal side effects may involve various combinations of tremors, postural unsteadiness, lack of or slowness of movement, cogwheel rigidity, expressionless face, drooling, infrequent blinking, shuffling gate, decreased arm swing, and rigidity of muscles in the limbs, neck, and trunk.

3. Indomethacin (Indocin, Indocin SR)

Risk: “Of all the nonsteroidal anti-inflammatory drugs, indomethacin produces the most central nervous system side effects and should therefore be avoided in the elderly.” The most common side effects (in order of frequency of occurrence) are

headache (10%), dizziness (3-9%), and vertigo, somnolence, depression, and fatigue (1-3%).

Exception: It is considered acceptable to use indomethacin for short term (e.g., 1 week) treatment of an acute episode of gouty arthritis.

4. Dipyridamole (Persantine)

Risk: “Dipyridamole frequently cause orthostatic hypotension in the elderly. It has been proven beneficial only in patients with artificial heart valves. Whenever possible, its use in the elderly should be avoided.

5. Reserpine (Serpasil)

Combination products such as Ser-Ap-Es, Serathide, Hydropres, Unipres, Uni-serp, Diutensen-R, Metatensin #2 & #4, Diupres, Hydroserpine, Hydromox-R, Regroton, Renese-R, Salutensin.

Risk: “Reserpine imposes unnecessary Risks in the elderly, inducing depression, impotence, sedation, and orthostatic hypotension. Safer alternatives exist.”

6. Diphenhydramine (Benadryl)

Note: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for these drugs under: D. Drugs for Sleep Induction. The surveyor should use that guideline if diphenhydramine is being used as a hypnotic. If diphenhydramine is being used as an antihistamine, this guideline should be used.

Risk: “Diphenhydramine is potently anticholinergic and usually should not be used as a hypnotic in the elderly. When used to treat or prevent allergic reactions, it should be used in the smallest dose and with great caution.” Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: For treatment of allergies, review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

7. Ergot Mesyls (Hydergine), Cyclospasmol

Risk: “Hydergine and the central vasodilators have not been shown to be effective, in the doses studied for treatment of dementia or any other condition.”

8. Muscle Relaxants

Muscle Relaxants such as Methocarbamol (Robaxin), Carisoprodol (Soma), Chlorzoxazone (Paraflex) Metaxalone (Skelaxin), Cyclobenzaprine (Flexeril), Dantrolene (Dantrium), Orphenadrine (Norflex, Banflex, Myotrol).

Risk: “Most muscle relaxants are poorly tolerated by the elderly, leading to anticholinergic side effects, sedation, and weakness.” Anticholinergic side effects include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

9. Antihistamines

Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril, Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleennamine (PBZ), Dexchlorpheniramine (Polaramine).

Risk: “All nonprescription and many prescription antihistamines have a potent anticholinergic properties.” Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. When used to treat or prevent allergic reactions, antihistamines should be used in the smallest possible dose, and for the shortest period of time, and with great caution.

Diagnosis/Drug Combinations with High Potential for Less Severe Outcomes

1. Diabetes

Drugs: Corticosteroids such as Beclomethasone (Beclovent, Vanceril), Betamethasone (Celestone), Cortisone Acetate (Cortone Acetate), Dexamethasone (Decadron, Dexone), Hydrocortisone (Cortef), Methylprednisolone (Medrol), Prednisolone (many brands), Prednisone (many brands).

Risk: “May worsen diabetic control, if recently started.”

If Recently Started: The panelists for the Beers’ study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should pay close attention to obtaining a rationale for its use during that time. The surveyor should be responsible for indepth investigation to determine when the drug was actually started. It should be noted that rapid withdrawal of these medicines in a steroid-dependent person can cause serious side effects.

2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease.

Drugs: Aspirin in excess of 325 mg. per day.

Risk: “May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD).”

Note: The panelists did not believe that enteric coated aspirin would be beneficial since aspirin exacerbates these conditions primarily through its systemic effects rather than its local effects.

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Drugs: Potassium supplements such as Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K or Ten K. This includes liquid oral dosage forms which, if used, should be administered after meals with an optimal amount of water or fruit juice (depending on the resident's fluid restrictions) to decrease the potential of gastric distress or bad taste as much as possible.

Risk: "May cause gastric irritation with symptoms similar to ulcer disease."

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Exception: Use of these medications to treat low potassium levels until they return to normal range if determined by the prescriber that use of fresh fruits and vegetables or other dietary supplementation is not adequate or possible.

3. Seizures or Epilepsy

Drugs: Clozapine (Clozaril), Chlorpromazine (Thorazine), Thioridazine (Mellaril), Chlorprothixene (Taractan), Metoclopramide (Reglan), Fluphenazine (Prolixin, Permitil), Perphenazine (Trilafon), Mesoridazine (Serentil), Prochlorperazine (Compazine), Promazine (Sparine), Trifluoperazine (Stelazine), Triflupromazine (Vesprin), Haloperidol (Haldol), Loxapine (Loxitane), Molindone (Moban), Olanzapine (Zyprexa), Pimozide (Orap), Risperidone (Risperdal), Thiothixene (Navane), Quetiapine (Seroquel).

Risk: "May lower seizure threshold."

Potential Side Effect: Increased risk of seizure activity.

Exception: Use of these drugs within the already established CMS guidelines (483.25(1)) for a 72 hour period or less, when treating acute psychosis, such that the individual is a danger to self or others.

4. Benign Prostatic Hypertrophy (BPH)

Drugs: Narcotic drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Risk: "Anticholinergic drugs may impair micturition and cause obstruction in men with BPH."

Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, low back pain.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Drugs: Flavoxate (Urispas), Oxybutynin (Ditropan), Bethanechol (Urecholine, Duvoid).

Risk: “Bladder relaxants may cause obstruction in persons with BPH.”

Potential Side Effects: Urinary retention, incontinence, hesitancy, reflux, hydronephrosis.

5. Constipation

Drugs: Anticholinergic antihistamines such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril & Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleminamine (PBZ), Dexchlorpheniramine (Polaramine).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anti-Parkinson medications such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemadren), Biperiden (Akineton).

GI Antispasmodics such as Dicyclomine (Bentyl), Hyoscyamine (Levsin & Levsinex), Propantheline (Pro-Banthine), Belladonna Alkaloids (Donnatal), Clidinium containing products such as Librax.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anticholinergic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

Narcotic Drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

6. Insomnia

Drugs:

- Decongestants such as Phenylephrine (Duo-Medihaler), Phenylpropanolamine (Genex), Pseudoephedrine (Novafed, Sudafed, Triaminic AM, Efidac/24);
- Theophylline (Elixophyllin, Bronkodyl, Theo-Dur, Slo-Bid);
- Desipramine (Pertofrane, Norpramin);
- Selective Serotonin Reuptake Inhibitors such as Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft);
- Methylphenidate (Ritalin);
- Monamine Oxidase Inhibitors (MAOIs) such as Phenelzine (Nardil), Tranylcypromine (Parnate); and
- Beta Agonists such as Isoproterenol (Isuprel), Albuterol (Proventil), Bitolterol (Tornalate), Terbutaline (Brethine).

Risk: “May cause or worsen insomnia.”

(The surveyor should consider that insomnia is often a symptom of untreated depression and Chronic Obstructive Pulmonary Disease (COPD.))

F430

§483.60(c)(2)

these reports must be acted upon.

Interpretive Guidelines §483.60(c)(2)

The director of nursing and the attending physicians are not required to agree with the pharmacist’s report, nor are they required to provide a rationale for their “acceptance” or “rejection” of the report. They must, however, act upon the report. This may be accomplished by indicating acceptance or rejection of the report and signing their names. The facility is encouraged to provide the medical director with a copy of drug regimen review reports and to involve the medical director in reports that have not been acted upon.

F431

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

Interpretive Guidelines §483.60(d)

This section imposes currently accepted labeling requirements on **facilities**, even though the pharmacies will be immediately responsible for accomplishing the task.

The critical elements of the drug label in a long-term care facility are the name of the drug and its strength.

The names of the resident and the physician do not have to be on the label of the package, but they must be identified with the package in such a manner as to assure that the drug is administered to the right patient.

All drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container. "When applicable" means that expiration dates must be on the labels of drugs used in long term care facilities unless State law stipulates otherwise.

F432

§483.60(e) Storage of Drugs and Biologicals

- (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.
- (2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Interpretive Guidelines §483.60(e)

Compartments in the context of these regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for authorized personnel to have access to keys must be determined by the facility management in accordance with Federal, State, and local laws and facility practices. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs.

F441

§483.65 Infection Control

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an infection control program under which it--

- (1) Investigates, controls, and prevents infections in the facility;
- (2) Decides what procedures, such as isolation should be applied to an individual resident; and
- (3) Maintains a record of incidents and corrective actions related to infections.

Intent §483.65(a)

The intent of this regulation is to assure that the facility has an infection control program which is effective for investigating, controlling, and preventing infections. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

Interpretive Guidelines §483.65(a)

The facility's infection control program must have a system to monitor and investigate causes of infection (nosocomial and community acquired) and manner of spread. A facility should, for example, maintain a separate record on infection that identifies each resident with an infection, states the date of infection, the causative agent, the origin or site of infection, and describes what cautionary measures were taken to prevent the spread of the infection within the facility. The system must enable the facility to analyze clusters, changes in prevalent organisms, or increases in the rate of infection in a timely manner.

F442**§483.65(b) Preventing Spread of Infection**

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

F443

§483.65(b)(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

F444

§483.65(b)(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

Intent §483.65(b)(3)

The intent of this regulation is to assure that staff use appropriate handwashing techniques to prevent the spread of infection from one resident to another.

Interpretive Guidelines §483.65(b)(3)

Procedures must be followed to prevent cross-contamination, including handwashing or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be readily available to staff. The facility should follow the CDC's "Guideline for Handwashing and Hospital Environmental Control, 1985," for handwashing.

F514**§483.75(l) Clinical Records**

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

- (i) Complete;
- (ii) Accurately documented;

- (iii) Readily accessible; and
- (iv) Systematically organized.

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete, and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up:

- There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility.
- The computer has built-in safeguards to minimize the possibility of fraud.
- Each person responsible for an attestation has an individualized identifier.
- The date and time is recorded from the computer's internal clock at the time of entry
- An entry is not to be changed after it has been recorded.
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

F520

§483.75(o) Quality Assessment and Assurance

- (1) A facility must maintain a quality assessment and assurance committee consisting of--
- (i) The director of nursing services;

- (ii) A physician designated by the facility; and
- (iii) At least 3 other members of the facility's staff.

F521

(2) The quality assessment and assurance committee -

- (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
- (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.