

Antipsychotic Use Survey Tool – Supplemental Guidance

Commonly prescribed antipsychotic medications (brand name and/or generic):

First generation (typical) antipsychotic:

chlorpromazine (generic only)
 fluphenazine (generic only)
 Haldol (haloperidol)
 Loxitane (loxapine)
 Moban (molindone)
 Navane (thiothixene)
 perphenazine (generic only)
 thioridazine (generic only)
 trifluoperazine (generic only)

Second generation (atypical) antipsychotic:

Abilify (aripiprazole)
 Clozaril (clozapine)
 Fanapt (iloperidone)
 Geodon (ziprasidone)
 Invega (paliperidone)
 Risperdal (risperidone)
 Seroquel (quetiapine)
 Zyprexa (olanzapine)
Combination antidepressant and antipsychotic medication:
 Symbyax (Prozac (fluoxetine) & Zyprexa)

F329 TABLE 1: ANTIPSYCHOTIC DOSAGE

If the resident has dementing illness, with associated behavioral symptoms, assess for the following total daily dose:

| Medication | Total Daily Dosage |
|--------------------------------|--------------------|
| Abilify (aripiprazole) | 10 mg |
| chlorpromazine (generic only) | 75 mg |
| Clozaril (clozapine) | 50 mg |
| Fanapt (iloperidone) | * |
| fluphenazine (generic only) | 4 mg |
| Geodon (ziprasidone) | * |
| Haldol (haloperidol) | 2 mg |
| Invega (paliperidone) | * |
| Loxitane (loxapine) | 10 mg |
| Moban (molindone) | 10 mg |
| Navane (thiothixene) | 7 mg |
| perphenazine (generic only) | 8 mg |
| Risperdal (risperidone) | 2 mg |
| Seroquel (quetiapine) | 150 mg |
| thioridazine (generic only) | 75 mg |
| Trifluoperazine (generic only) | 8 mg |
| Zyprexa (olanzapine) | 7.5 mg |

* Not customarily used for the treatment of dementia behavioral symptoms

MONITORING FOR ADVERSE CONSEQUENCES

Potential antipsychotic adverse effects:

- anticholinergic effects (dry mouth, constipation, blurred vision, drowsiness, dizziness, increased heart rate, urinary retention, delirium)
- increase in total cholesterol and triglycerides
- akathisia (inability to sit still, motor restlessness)

- parkinsonism (tremors, rigidity of movement, shuffling gait, droopy posture or masklike facies)
- neuroleptic malignant syndrome (hyperthermia with extrapyramidal and autonomic disturbances that may result in death)
- blood sugar elevation
- orthostatic hypotension
- falls
- weight change
- tardive dyskinesia (abnormal involuntary movements of the tongue, lips, face, trunk and extremities)
- lethargy/sedation

WARNINGS and PRECAUTIONS

Metabolic Changes

- Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Weight Gain

- Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Antipsychotic FDA boxed warnings:

FDA ALERT [6/16/2008]: FDA is notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis.

In April 2005, FDA notified healthcare professionals that patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death. Since issuing that notification, FDA has reviewed additional information that indicates the risk is also associated with conventional antipsychotics.

Antipsychotics are not indicated for the treatment of dementia-related psychosis.

Source: <http://www.fda.gov/Drugs/default.htm>

Ziprasidone (Geodon®):

Ziprasidone use should be avoided in combination with other drugs that are known to prolong the QTc interval.... Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QTc interval. Such drugs should not be prescribed with ziprasidone. Ziprasidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Thioridazine (Mellaril®):

Mellaril® (thioridazine hcl) has been shown to prolong the qtc interval in a dose related manner, and drugs with this potential, including mellaril, have been associated with torsade de pointes-type arrhythmias and sudden death. Due to its potential for significant, possibly life-threatening, proarrhythmic effects, mellaril should be reserved for use in the treatment of schizophrenic patients who fail to show an acceptable response to adequate courses of treatment with other antipsychotic drugs, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs.

Additional FDA boxed warning information relevant to antipsychotic medications available at the following link:

<https://blackboxrx.com/>

F222 (§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.

F329 (§483.25(l) 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 combination of the reasons above.

2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

- (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
- (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioural interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

F329: Antipsychotic Gradual Dose Reduction (GDR)

Clinically contraindicated is:

(A) For treatment of behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; **AND**
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would likely impair the resident's function or increase distressed behavior.

(B) For treatment of a psychiatric disorder other than behavioral symptoms related to dementia the GDR may be considered contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would likely impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; **OR**
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would likely impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

INFORMED CONSENT

T22 § 72527 Patients' Rights

(a) Patients have the rights enumerated in this section and the facility shall ensure that these rights are not violated. The facility shall establish and implement written policies and procedures which include these rights and shall make a copy of these policies available to the patient and to any representative of the patient. The policies shall be accessible to the public upon request.

Patients shall have the right:

(3) To be fully informed by a physician of his or her total health status and to be afforded the opportunity to participate on an immediate and ongoing basis in the total plan of care including the identification of medical, nursing and psychosocial needs and the planning of related services.

(4) To consent to or refuse any treatment...

(5) To receive all information that is material of an individual patient's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function shall include the disclosure of information listed in Section 72528(b).

(23) To be free from psychotherapeutic drugs...used for the purpose of patient discipline or staff convenience and to be free from psychotherapeutic drugs used as a chemical restraint...except in an emergency which threatens to bring immediate injury to the patient or others. If a chemical restraint is administered during an emergency, such medication shall be only that which is required to treat the emergency condition and shall be provided in ways that are least restrictive of the personal liberty of the patient and used only for a specified and limited period of time.

(e) Patients' rights policies and procedures established under this section concerning consent, informed consent and refusal or treatments or procedures shall include, but not be limited to the following:

(1) How the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to the administration of psychotherapeutic drugs...

T22 § 72528 Informed Consent Requirements

(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

- (1) The reason for the treatment and the nature and seriousness of the patient's illness.
 - (2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.
 - (3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.
 - (4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.
 - (5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
 - (6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.
- (c) Before initiating the administration of psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, facility staff shall verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the patient's health record.
- (d) This section shall not be construed to require obtaining informed consent each time a treatment or procedure is administered unless material circumstances or risks change.
- (e) There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of physicians of good standing in similar circumstances.
- (f) Notwithstanding Sections 72527(a)(5) and 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the patient's health record:
- (1) That the patient or patient's representative specifically requested that he or she not be informed of the risk of the recommended treatment or procedure. This request does not waive the requirement for providing the other material information concerning the treatment or procedure.
 - (2) That the physician relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the patient that the patient would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a patient's representative gave informed consent as set forth herein.

H&SC 1418.8 Medical interventions requiring informed consent; resident lacking decision-making capacity; interdisciplinary team review (aka Epple Act regarding informed consent for an incapacitated resident):

- (a) If the attending physician and surgeon of a resident in a skilled nursing facility or intermediate care facility prescribes or orders a medical intervention that requires that informed consent be obtained prior to administration of the medical intervention, but is unable to obtain informed consent because the physician and surgeon determines that the resident lacks capacity to make decisions concerning his or her health care and that there is no person with legal authority to make those decisions on behalf of the resident, the physician and surgeon shall inform the skilled nursing facility or intermediate care facility.
- (b) For purposes of subdivision (a), a resident lacks capacity to make a decision regarding his or her health care if the resident is unable to understand the nature and consequences of the proposed medical intervention, including its risks and benefits, or is unable to express a preference regarding the intervention. To make the determination regarding capacity, the physician shall interview the patient, review the patient's medical records, and consult with skilled nursing or intermediate care facility staff, as appropriate, and family members and friends of the resident, if any have been identified.
- (c) For purposes of subdivision (a), a person with legal authority to make medical treatment decisions on behalf of a patient is a person designated under a valid Durable Power of Attorney

for Health Care, a guardian, a conservator, or next of kin. To determine the existence of a person with legal authority, the physician shall interview the patient, review the medical records of the patient, and consult with skilled nursing or intermediate care facility staff, as appropriate, and with family members and friends of the resident, if any have been identified.

(d) The attending physician and the skilled nursing facility or intermediate care facility may initiate a medical intervention that requires informed consent pursuant to subdivision (e) in accordance with acceptable standards of practice.

(e) Where a resident of a skilled nursing facility or intermediate care facility has been prescribed a medical intervention by a physician and surgeon that requires informed consent and the physician has determined that the resident lacks capacity to make health care decisions and there is no person with legal authority to make those decisions on behalf of the resident, the facility shall, except as provided in subdivision (h), conduct an interdisciplinary team review of the prescribed medical intervention prior to the administration of the medical intervention. The interdisciplinary team shall oversee the care of the resident utilizing a team approach to assessment and care planning, and shall include the resident's attending physician, a registered professional nurse with responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs, and, where practicable, a patient representative, in accordance with applicable federal and state requirements. The review shall include all of the following:

(1) A review of the physician's assessment of the resident's condition.

(2) The reason for the proposed use of the medical intervention.

(3) A discussion of the desires of the patient, where known. To determine the desires of the resident, the interdisciplinary team shall interview the patient, review the patient's medical records, and consult with family members or friends, if any have been identified.

(4) The type of medical intervention to be used in the resident's care, including its probable frequency and duration.

(5) The probable impact on the resident's condition, with and without the use of the medical intervention.

(6) Reasonable alternative medical interventions considered or utilized and reasons for their discontinuance or inappropriateness.

(f) A patient representative may include a family member or friend of the resident who is unable to take full responsibility for the health care decisions of the resident, but who has agreed to serve on the interdisciplinary team, or other person authorized by state or federal law.

(g) The interdisciplinary team shall periodically evaluate the use of the prescribed medical intervention at least quarterly or upon a significant change in the resident's medical condition.

(h) In case of an emergency, after obtaining a physician and surgeon's order as necessary, a skilled nursing or intermediate care facility may administer a medical intervention that requires informed consent prior to the facility convening an interdisciplinary team review. If the emergency results in the application of physical or chemical restraints, the interdisciplinary team shall meet within one week of the emergency for an evaluation of the medical intervention.

(i) Physicians and surgeons and skilled nursing facilities and intermediate care facilities shall not be required to obtain a court order pursuant to Section 3201 of the Probate Code prior to administering a medical intervention which requires informed consent if the requirements of this section are met.

(j) Nothing in this section shall in any way affect the right of a resident of a skilled nursing facility or intermediate care facility for whom medical intervention has been prescribed, ordered, or administered pursuant to this section to seek appropriate judicial relief to review the decision to provide the medical intervention.

(k) No physician or other health care provider, whose action under this section is in accordance with reasonable medical standards, is subject to administrative sanction if the physician or health care provider believes in good faith that the action is consistent with this section and the desires of the resident, or if unknown, the best interests of the resident.

(l) The determinations required to be made pursuant to subdivisions (a), (e), and (g), and the basis for those determinations shall be documented in the patient's medical record and shall be made available to the patient's representative for review.

H&SC 1418.9 Order of antipsychotic medication; duties of attending physician and surgeon or resident; informed consent; notification requirements; definitions

(a) If the attending physician and surgeon of a resident in a skilled nursing facility prescribes, orders, or increases an order for an antipsychotic medication for the resident, the physician and surgeon shall do both of the following:

(1) Obtain the informed consent of the resident for purposes of prescribing, ordering, or increasing an order for the medication.

(2) Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record. If the resident consents to the notice, the physician and surgeon shall make reasonable attempts, either personally or through a designee, to notify the interested family member, as designated in the medical record, within 48 hours of the prescription, order, or increase of an order.

(b) Notification of an interested family member is not required under paragraph (2) of subdivision (a) if any of the following circumstances exist:

(1) There is no interested family member designated in the medical record.

(2) The resident has been diagnosed as terminally ill by his or her physician and surgeon and is receiving hospice services from a licensed, certified hospice agency in the facility.

(3) The resident has not consented to the notification.

(c) As used in this section, the following definitions shall apply:

(1) "Resident" means a patient of a skilled nursing facility who has the capacity to consent to make decisions concerning his or her health care, including medications.

(2) "Designee" means a person who has agreed with the physician and surgeon to provide the notice required by this section.

(3) "Antipsychotic medication" means a medication approved by the United States Food and Drug Administration for the treatment of psychosis.

(4) "Increase of an order" means an increase of the dosage of the medication above the dosage range stated in a prior consent from the resident.

(d) This section shall not be construed to require consent from an interested family member for an attending physician and surgeon of a resident to prescribe, order, or increase an order for antipsychotic medication.

H & SC 1424. Citations issued pursuant to this chapter shall be classified according to the nature of the violation and shall indicate the classification on the face thereof.

(a) In determining the amount of the civil penalty, all relevant facts shall be considered, including, but not limited to, the following:

(1) The probability and severity of the risk that the violation presents to the patient's or resident's mental and physical condition.

(2) The patient's or resident's medical condition.

(3) The patient's or resident's mental condition and his or her history of mental disability or disorder.

(4) The good faith efforts exercised by the facility to prevent the violation from occurring.

(5) The licensee's history of compliance with regulations.

(b) Relevant facts considered by the department in determining the amount of the civil penalty shall be documented by the department on an attachment to the citation and available in the public record.

This requirement shall not preclude the department or a facility from introducing facts not listed on the citation to support or challenge the amount of the civil penalty in any proceeding set forth in Section 1428.

(c) Class "AA" violations are violations that meet the criteria for a class "A" violation and that the state department determines to have been a direct proximate cause of death of a patient or resident of a long-term health care facility. Except as provided in Section 1424.5, a class "AA" citation is subject to a civil penalty in the amount of not less than five thousand dollars (\$5,000) and not exceeding twenty-five thousand dollars (\$25,000) for each citation. In any action to enforce a citation issued under this subdivision, the state department shall prove all of the following:

(1) The violation was a direct proximate cause of death of a patient or resident.

(2) The death resulted from an occurrence of a nature that the regulation was designed to prevent.

(3) The patient or resident suffering the death was among the class of persons for whose protection the regulation was adopted. If the state department meets this burden of proof, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed. Except as provided in Section 1424.5, for each class "AA" citation within a 12-month period that has become final, the state department shall consider the suspension or revocation of the facility's license in accordance with Section 1294. For a third or subsequent class "AA" citation in a facility within that 12-month period that has been sustained, the state department shall commence action to suspend or revoke the facility's license in accordance with Section 1294.

(d) Class "A" violations are violations which the state department determines present either (1) imminent danger that death or serious harm to the patients or residents of the long-term health care facility would result therefrom, or (2) substantial probability that death or serious physical harm to patients or residents of the long-term health care facility would result therefrom. A physical condition or one or more practices, means, methods, or operations in use in a long-term health care facility may constitute a class "A" violation. The condition or practice constituting a class "A" violation shall be abated or eliminated immediately, unless a fixed period of time, as determined by the state department, is required for correction. Except as provided in Section 1424.5, a class "A" citation is subject to a civil penalty in an amount not less than one thousand dollars (\$1,000) and not exceeding ten thousand dollars (\$10,000) for each and every citation.

If the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed.

(e) Except as provided in paragraph (4) of subdivision (a) of Section 1424.5, class "B" violations are violations that the state department determines have a direct or immediate relationship to the health, safety, or security of long-term health care facility patients or residents, other than class "AA" or "A" violations. Unless otherwise determined by the state department to be a class "A" violation pursuant to this chapter and rules and regulations adopted pursuant thereto, any violation of a patient's rights as set forth in Sections 72527 and 73523 of Title 22 of the California Code of Regulations, that is determined by the state department to cause or under circumstances likely to cause significant humiliation, indignity, anxiety, or other emotional trauma to a patient is a class "B" violation. A class "B" citation is subject to a civil penalty in an amount not less than one hundred dollars (\$100) and not exceeding one thousand dollars (\$1,000) for each and every citation. A class "B" citation shall specify the time within which the violation is required to be corrected. If the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed. In the event of any citation under this paragraph, if the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed.