

Multi Site Breakfast - March 3, 2016
Natick, Peabody, Duxbury, and Westfield, Massachusetts



Antipsychotics and Dementia:

What attorneys and geriatric advocates need to know about the (over) use of antipsychotic medications with memory loss residents in a facility setting.

Nursing homes have for many years used psychotropic medicines to modify the behavior of residents who suffer from Alzheimer's disease, memory loss, and dementia. Medicare surveys in Massachusetts and other states show 20% of nursing residents who are on antipsychotic meds have NOT been diagnosed with a psychotic condition.¹

Clients, and their attorneys, who are aware of the alternatives to behavior modification medication can help protect the quality of life for the memory loss patient. Medicaid planning and efforts to protect assets require an understanding of the progressing needs of the memory loss patient, and the many resources that are available to meet those needs. Without a sound understanding of the services available to the memory loss patient at home or in assisted living, a resident could end up needing a nursing home admission, where chemical and physical restraints are applied.

Each stage of memory loss requires awareness of how to direct the client and family members toward appropriate resources. Severe consequences can result when a family member who has authority to act under power of attorney and health care documents fails to understand and anticipate the needs of the memory loss client.

When family members, attorneys and judges do understand legal planning as part of an appropriate response to each stage of memory loss, the client's dignity and quality of life can be preserved. The client can be protected and redirected from erratic behaviors that would otherwise lead to physical and chemical restraints in a nursing home. This information is a vital part of formulating a plan, and essential in any case where planning involves a 5 year Medicaid look back period.

An editorial in the [February, 2009 Lancet](#) concluded that: "High levels of prescription of antipsychotic drugs for neuropsychiatric symptoms in dementia are putting many vulnerable patients at risk of death and other adverse events. . . . The risks and benefits of prescribing antipsychotics to patients with dementia need to be carefully balanced and these drugs should be used only if alternative strategies do not work. To protect the health and dignity of people with dementia and reduce the use of antipsychotic drugs, approaches that make the needs of patients central to decisions about care should be promoted."

¹Statistics for April-June 2010 at [MDS Quality Measure/Indicator Report on Psychotropic Drug Use](#)
Nursing home drug use puts many at risk. [Boston Globe, March 8, 2010](#)

When viewing the electronic PDF file, click on each topic in the Table of Contents to read more.

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Examples of Antipsychotic medications administered to Massachusetts nursing home residents

These medications, with Black Box warnings, are listed in the Physicians Desk Reference, pdrhealth.com

Abilify (aripiprazole)

A medicine used to treat schizophrenia. It is also be used to treat bipolar disorder (alone or in combination with lithium or valproate), major depressive disorder (in combination with other antidepressants), and irritability associated with autism.

More common side effects may include: drowsiness, fatigue, vomiting, fever, drooling, decreased appetite, increased salivation, uncontrolled movements (such as shaking or muscle stiffness), tiredness.

Abilify is not approved to treat mental problems caused by dementia (an illness involving loss of memory and judgment, and confusion) in the elderly. It can be life-threatening when used in elderly people with mental problems caused by dementia.

Haldol (haloperidol)

Haldol decanoate is a medication used to treat schizophrenia when oral therapy is no longer possible. It may cause tardive dyskinesia, a movement disorder characterized by slow or jerky facial or body movements. Older adults, especially women, appear to be at greater risk. It may cause neuroleptic malignant syndrome, a life-threatening brain disorder.

Who should not take Haldol Decanoate?

Elderly patients with dementia-related psychosis, or patients with Parkinson's disease or a condition known as severe toxic central nervous system depression should not receive Haldol decanoate.

Risperdal (risperidone)

The Food and Drug Administration (FDA) first approved Risperdal in 2002 to treat schizophrenia in adults and youths at least 13 years old. Schizophrenia is a mental illness that can cause people to lose interest in life and develop abnormal thoughts and emotions.

Risperdal is not approved to treat mental problems caused by dementia (an illness involving loss of memory and judgment, and confusion) in the elderly. It can be life-threatening when used in elderly people with mental problems caused by dementia.

More common side effects may include: abdominal (stomach area) pain, anxiety, blurred vision, common cold, constipation, diarrhea, dizziness, dry mouth, increased saliva, increased appetite, indigestion, involuntary muscle movements, nausea, rash, shaking, sleepiness, stuffy nose, throat pain, tiredness, upper respiratory infection, vomiting, weight gain.

The manufacturer marketed Risperdal as a treatment for older people with agitation from dementia, which is not an FDA-approved use of the medication. The manufacturer had to pay a fine for misbranding the drug. The combined criminal plea agreement with the Justice Department and a civil settlement totaled more than \$1.67 billion.

Seroquel (quetiapine)

Seroquel is a medicine used to treat schizophrenia. This medication can also be used to treat bipolar disorder alone or in combination with lithium or divalproex. Also, Seroquel XR is used to treat major depressive disorder in combination with other antidepressants.

Seroquel XR is not approved to treat mental problems caused by dementia (an illness involving loss of memory and judgment, and confusion) in the elderly. It can be life-threatening when used in elderly people with mental problems caused by dementia.

Medicare Laws that govern Nursing homes and hospitals

Under Federal Medicare law, patients have 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. Restraints may only be imposed—(I) to ensure the physical safety of the resident or other residents, and (II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used.

42 U.S.C. § 1395i-3(c)(1)(A)(ii) and [42 U.S.C. §1396r\(c\)\(1\)\(A\)\(II\)](#).

Guidance issued to government Surveyors for Long Term Care Facilities lists the serious conditions that justify antipsychotic use, and the inadequate indications for administering antipsychotic medications: They should not be used if the only indication is one or more of the following: 1) wandering; 2) poor self-care; 3) restlessness; 4) impaired memory; 5) mild anxiety; 6) insomnia; 7) unsociability; 8) inattention or indifference to surroundings; 9) fidgeting; 10) nervousness; 11) uncooperativeness; or 12) verbal expressions or behavior that are not due to the conditions listed under "Indications" and do not represent a danger to the resident or others.

[Guidance issued by the Centers for Medicare & Medicaid Services, State Operations Manual, Appendix PP](#) at 387 [PDF document page 434]. When antipsychotics are used without monitoring they may be considered unnecessary medications because of inadequate monitoring. Id. at 389.

Nursing Homes Compliance Program and staffing guidelines

Personal injury attorneys use federal directives as evidence of the standard of care in nursing homes. The Office of Inspector General (OIG) has developed compliance program guidance (CPG) that recommends the steps each facility must take in assessing risk areas. This guidance is based on Medicare and Medicaid nursing facility payment systems and regulations, industry practices, and current enforcement priorities. The OIG guidance is at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf

Sufficient Staffing, Comprehensive Resident Care Plans, Medication Management, and Appropriate Use of Psychotropic Medications are the top four risk factors for "Nursing facilities that fail to make quality a priority, and consequently fail to deliver quality health care." Based on the OIG's enforcement and compliance monitoring activities, inappropriate use of psychotropic medications is a risk for nursing home residents because of the "prohibition against inappropriate use of chemical restraints and the requirement to avoid unnecessary drug usage."

Facilities have affirmative obligations to ensure appropriate use of psychotropic medications. Specifically, nursing facilities must ensure that psychopharmacological practices comport with Federal regulations and generally accepted professional standards.

The facility is responsible for the quality of drug therapy provided in the facility. Federal law prohibits facilities from using any medication as a means of chemical restraint for “purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.”

In addition, resident drug regimens must be free from unnecessary drugs. For residents who specifically require antipsychotic medications, CMS regulations also require, unless contraindicated, that residents receive gradual dose reductions and behavioral interventions aimed at reducing medication use.

In light of these requirements, nursing facilities should ensure that there is an adequate indication for the use of the medication and should carefully monitor, document, and review the use of each resident’s psychotropic drugs.

Working together, the attending physicians, medical director, consultant pharmacist, and other resident care providers play a critical role in achieving these objectives.

Compliance measures could include educating care providers regarding appropriate monitoring and documentation practices and auditing drug regimen reviews and resident care plans to determine if they incorporate an assessment of the resident’s “medical, nursing, and mental and psychosocial needs,” including the need for psychotropic medications for a specific medical condition.

The attending physicians, the medical director, the consultant pharmacist, and other care providers should collaborate to analyze the outcomes of care using the results of the drug regimen reviews, progress notes, and monitoring of the resident’s behaviors.

Pages 56838 – 39 antipsychotic medications recommended compliance, posted at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf

Medications that require Notice and Consent under MGL ch. 111, §72BB

The most recent effort to protect for nursing home residents is at [Mass. Gen. Laws ch. 111 §72BB](#). The law requires nursing homes to get consent from a resident, or Health Care Agent or Guardian, before administering psychotropic medication.

Psychotropic (also called psychoactive or psychotherapeutic) drugs contain powerful chemicals that act on the brain to change a person's mood, personality, behavior, and/or level of consciousness.

There are 4 classes of psychotropic drugs: antipsychotic, antidepressant, anti-anxiety, and sedative/hypnotic.

Antipsychotics, listed in the right hand column on page 1 of the *Schedule of Psychotropic Drugs* in Attachment A, have a potentially dangerous, sometimes lethal, impact on the elderly, and have been inappropriately used to control nursing home residents with dementia in Massachusetts and in other states.

Other classes of psychotropic drugs listed on this Schedule of Psychotropic Drugs can also have a serious impact on the elderly.

M.G.L. ch. 111, S 72BB requires informed consent on all of these psychotropic drugs.

As explained in the Department of Public Health Circular Letter: DHCQ 16-2-653, only the *Antipsychotic* drugs require special Probate Court authorization (Rogers) if the patient is under a Guardianship.

Otherwise, a Health Care Agent can authorize any of these medications, including the antipsychotic drugs.

Attachment A
Schedule of Psychotropic Drugs
(Updated August, 2015)

Classes of Medications Frequently Used for Psychiatric Indications (page 1 of 2)

Documentation of Informed Consent is required for any medication that is used in the treatment of a psychiatric diagnosis or symptom, whether or not the medication is included in this list. Refer to physician order for determination of indication for use. (See **Special Considerations Regarding the Use of Antipsychotic Drugs**, discussed on page 2 of Circular Letter DHCQ 16-2-653, above)

Documentation of Informed Consent is still required when a medication on this list is used for an off-label or alternate clinical purpose. Such use does not alter its classification on this list. Note that the generic name is listed first, with the brand name in parentheses.

Antidepressants

amitriptyline (Elavil)
amoxapine (Asendin)
bupropion (Wellbutrin, Wellbutrin SR)
bupropion (Wellbutrin XL)
citalopram (Celexa)
desipramine (Norpramin)
desvenlafaxine (Pristiq, Khedezla)
doxepin (Sinequan)
duloxetine (Cymbalta)
escitalopram (Lexapro)
fluoxetine (Prozac)
imipramine (Tofranil)
maprotiline (Ludiomil)
mirtazapine (Remeron, Remeron SolTab)
nefazodone (Serzone)
nortriptyline (Pamelor, Aventyl)
paroxetine (Paxil, Paxil CR)
protriptyline (Vivactil)
sertraline (Zoloft)
trazodone (Desyrel)
trimipramine (Surmontil)
venlafaxine (Effexor, Effexor XR)
vilazodone (Viibryd)
vortioxetine (Brintellix)

Anxiolytics/Sedatives/Hypnotics

alprazolam (Xanax, Xanax XR)
buspirone (BuSpar)
chlordiazepoxide (Librium)
clonazepam (Klonopin)
clorazepate (Tranxene)
diazepam (Valium)
diphenhydramine (Benadryl)
eszopiclone (Lunesta)
flurazepam (Dalmane)
hydroxyzine (Atarax, Vistaril)
lorazepam (Ativan)
oxazepam (Serax)
pentobarbital (Nembutal)
ramelteon (Rozerem)
temazepam (Restoril)
triazolam (Halcion)
zaleplon (Sonata)

zolpidem (Ambien)

Antipsychotics

aripiprazole (Abilify, Abilify Discmelt)
Aripiprazole (AbilifyMaintena)
asenapine (Saphris)
chlorpromazine (Thorazine)
clozapine (Clozaril, Fazaclor, Versacloz)
Reserve droperidol (Inapsine)
fluphenazine (Prolixin)
fluphenazine decanoate (Prolixin D)
haloperidol (Haldol)
haloperidol decanoate (Haldol D)
iloperidone (Fanapt)
Reserve loxapine (Loxitane)
loxapine inhalant (Adasuve)
lurasidone (Latuda)
olanzapine (Zyprexa, Zyprexa Zydis)
olanzapine pamoate (Zyprexa Relprevv)
Reserve paliperidone (Invega)
paliperidone palmitate (Invega Sustenna)
perphenazine (Trilafon)
pimozide (Orap)
quetiapine (Seroquel)
quetiapine (Seroquel XR)
risperidone (Risperdal, RisperdalM-Tab)
risperidone (Risperdal Consta)
thioridazine (Mellaril)
thiothixene (Navane)
trifluoperazine (Stelazine)
ziprasidone (Geodon)

Stimulants

amphetamine/dextroamphetamine mixture
(Adderall, Adderall XR)
dexmethylphenidate (Focalin, Focalin XR)
dextroamphetamine (Dexedrine)
lisdexamfetamine (Vyvanse)
methamphetamine (Desoxyn)
methylphenidate (Ritalin, Ritalin SR, Concerta, Metadate, Metadate CD)
methylphenidate patch (Daytrana)
methylphenidate soln (Quillivant XR)

Attachment A
Schedule of Psychotropic Drugs
(Updated August, 2015)

Classes of Medications Frequently Used for Psychiatric Indications (page 2 of 2)

Chemical Dependency Adjuncts

acamprosate (Campral)
disulfiram (Antabuse)
naltrexone (ReVia, Vivitrol)
topiramate (Topamax)

Monoamine Oxidase Inhibitors

isocarboxazid (Marplan)
phenelzine (Nardil)
selegiline (Emsam)
tranylcypromine (Parnate)

Miscellaneous Drugs

atomoxetine (Strattera)
atenolol (Tenormin)
clomipramine (Anafranil)
clonidine (Catapres)
clonidine ER (Kapvay)
fluvoxamine (Luvox)
gabapentin (Neurontin)
guanfacine (Tenex)
guanfacine ER (Intuniv)
metoprolol (Lopressor)
nadolol (Corgard)
propranolol (Inderal)
reserpine (Serpasil)
naltrexone (ReVia)
olanzapine/fluoxetine (Symbyax)
pindolol (Visken)
prazosin (Minipress)

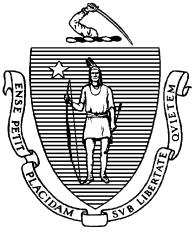
§72BB and Dep't of Public Health February 1, 2016 Circular Letter

Section 72BB says that the nursing home must disclose (i) the purpose for administering a psychotropic drug, (ii) dosage, and (iii) effects or side effects of the medication.

The Department of Public Health issued a Circular Letter on February 1, 2016 explaining how nursing homes and rest home will comply with the statute.

The Department of Public Health Circular also explains how the *Rogers* procedures established in [*Rogers v. Commissioner of Mental Health*](#), 390 Mass. 489, 508 - 509, 458 N.E.2d 308, 320 (1983) (convenience of facility staff is not an acceptable reason for using restraints) are now codified in the Massachusetts Uniform Probate Code, Mass. Gen. Laws ch. 190B, § 5-306A.

The requirements established in *Rogers* were intended to provide patients in Massachusetts with even greater protection than the protections afforded under Federal laws and regulations. See: Smith, "*Just Say No!*" *The Right to Refuse Psychotropic Medication in Long-Term Care Facilities* **13 Annals Health L** 1, 17 – 18 (2004). Do Massachusetts Courts meet the standards in the federal law and regulations?



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Circular Letter: DHCQ 16-2-653

TO: Long-Term Care Facility Administrators

FROM: Eric Sheehan, J.D. Interim Bureau Director
 Bureau of Health Care Safety and Quality

Sherman Lohnes, J.D. Director, Division of Health Care Facility Licensure and Certification

Jonathan M. Mundy, R.Ph, MBA, Director of the Office of Prescription Monitoring and Drug Control

DATE: February 1, 2016

SUBJECT: Informed Consent for Use of Psychotropic Medications in Long-term Care Facilities.

Section 72BB of chapter 111 of the General Laws (Section 72BB) was enacted by section 140 of chapter 165 of the acts of 2014 (FY2015 General Appropriations Act), becoming effective July 1, 2014. This section relates to documentation of informed consent prior to the administration of psychotropic medications, including antipsychotic medications, in Massachusetts-licensed long-term care facilities.

As a Medicare condition of participation, federal law requires that long-term care facilities document informed consent to the extent provided by state law, and Massachusetts long-term care regulations, 105 CMR 150.008(A)(4), require facilities to “comply with all Federal and State laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of drugs.”

This circular letter outlines the requirements for long-term care facilities under section 72BB, including guidance for the documentation of informed consent and the provision of a schedule of medications for which these procedures must be completed.

Section 72BB states as follows:

- (a) For the purposes of this section, the term 'facility' shall mean a nursing home, rest home or other long-term care facility.*
- (b) The department shall establish a schedule of psychotropic medications that shall not be administered to a resident by a facility without informed written consent.*
- (c) Prior to administering psychotropic medication listed on the schedule created under subsection (b), a facility shall obtain the informed written consent of the resident, the resident's health care proxy or the resident's guardian. Informed written consent shall be obtained on a form approved by the department, which shall include, at a minimum, the following information: (i) the purpose for administering the listed psychotropic drug; (ii) the prescribed dosage; and (iii) any known effect or side effect of the psychotropic medication. The written consent form shall be kept in the resident's medical record.*

The Department will consider a long term care facility to be in compliance with Section 72BB if the facility has policies and procedures that document the following:

1. Documentation of informed consent for prescribing psychotropic medications (as specified below), including but not limited to, drugs that treat depression, anxiety disorders, or attention deficit/hyperactivity disorder (official Department list included as Attachment A);
2. Appropriate training of staff regarding the *Rogers* requirements (discussed below), including the acknowledgment that, consistent with *Rogers*, guardians may not consent to the administration of antipsychotic medications.

In order to meet Section 72BB's requirements for documentation of informed consent, upon administration of any drug included on the Schedule of Psychotropic Medications (Attachment A), long term care facilities must complete the Department's prescribed form (Attachment B), and include the completed form in the resident's medical record. This form will demonstrate that the following were discussed with the resident or the resident's representative:

- (i) the purpose for administering the listed psychotropic drug;
- (ii) the prescribed dosage; and
- (iii) any known effect or side effect of the psychotropic medication.

While prescribers are not required to complete this process each and every time a resident is administered a dose of psychotropic medication, such procedures are required each time a new or renewed prescription falls outside the dosage range to which the resident or the resident's representative previously consented, or once a year, whichever is shorter.

Special Considerations Regarding the Use of Antipsychotic Drugs

The Department previously issued guidance on the consent requirements for the use of antipsychotic drugs. See Circular Letter DHCQ 03-04-433, issued in 2003, which is available at <http://www.mass.gov/eohhs/docs/dph/quality/hcq-circular-letters/ltc-facilities-0304433.pdf>. As noted, a valid health care proxy (HCP) (see M.G.L. c. 201D), also referred to as a Health Care

Agent, can consent to antipsychotic drugs without having to obtain a court-approved treatment plan required under *Rogers v. Commissioner of the Department of Mental Health*, 390 Mass. 489, 458 N.E.2d 308, (1983), if the following three conditions are met:

- (1) the health care proxy is activated by a physician after a determination that the resident is incompetent;
- (2) the resident has not limited the HCP agent's authority to consent to treatment with antipsychotic medications on the HCP form; and
- (3) the resident has not revoked or indicated an intent to revoke the HCP, for example, the resident has not refused to accept antipsychotic medication.

Please note that the above applies only to antipsychotic medications; a guardian or health care proxy can consent to other psychotropic medications. Antipsychotic medications are indicated separately on the Schedule of Psychotropic Medications (Attachment A). Please note that documentation of informed consent must be completed prior to administration of any medication appearing on the list.

In *Rogers*, the court established new rights relative to informed consent for individuals being treated with antipsychotic medications. Among these are that an individual has a constitutional right to refuse treatment with antipsychotic medications; that a guardian must be appointed for an individual following a determination that he or she is incompetent to consent to treatment; that the court must use a substituted judgment test comprised of six factors before authorizing a treatment plan; and that a guardian cannot make decisions about the use of antipsychotics because use of such medications is considered extraordinary treatment, but rather can monitor the implementation of the court-ordered treatment plan. In using the substituted judgment analysis, the court tries to recreate what an incompetent individual would choose if he or she were competent. The substituted judgment standard is now codified in the Massachusetts Uniform Probate Code, at M.G.L. c. 190B, § 5-306A. The court relies on a medical affidavit from the treating psychiatrist, or his or her testimony, as evidence in determining an individual's substituted judgment and treatment plan. Each *Rogers* treatment plan must be reviewed annually.

Rest Home Compliance

Facilities are reminded that 105 CMR 150.008 sets forth detailed requirements for the record-keeping, supervision, administration, labeling, and storage of all medication. Notwithstanding the language in Section 72BB that purports to treat rest homes and skilled nursing facilities in the same manner, Level IV facilities should refer to 105 CMR 150.008(C)(2) for the limited circumstances in which medications may be administered in a rest home, while complying with relevant procedures set forth in this letter.

Contact

If you have any questions about this guidance, please contact the Bureau of Health Care Safety and Quality, Division of Health Care Facilities Licensure and Certification, at sherman.lohnes@state.ma.us.

§72BB Notification Form

The Informed Consent Form promulgated on February 1, 2016 includes the statement "*it is possible that little or no adverse consequences may occur if the medication is administered.*" The statement is printed under "Risks" on the notice form, alongside the box where black box warnings should be listed by the facility. Will this statement detract from patient understanding or comprehending the significance of the black box warnings?

**Attachment B
Informed Consent Form**

This consent form shall be kept in the resident's medical record.

[Facility Name] CONSENT FORM FOR PSYCHOTROPIC ADMINISTRATION	(Affix resident information here)
---	-----------------------------------

NAME OF RESIDENT	
DATE OF DISCUSSION	
FACILITY REPRESENTATIVE NAME	
FACILITY REPRESENTATIVE TITLE	
LAST REVIEWED BY FACILITY	
MEDICATION PROPOSED/PRESCRIBED (Only one medication per form)	
DOSAGE RANGE	
PURPOSE OF MEDICATION	
RISKS (These risks may vary; and it is possible that little or no adverse consequences may occur if the medication is administered)	
BENEFITS (These benefits may vary; and it is possible that little or no adverse consequences may occur if the medication is not administered)	

Please indicate if resident or resident's representative refused consent.

By checking here and by my signature below, I give consent for the above named medication and anticipated dosage range. My signature also indicates that I understand the above listed risks and benefits of the medication. If the proposed medication is on the anti-psychotic list, evidence of substituted judgment may be required.

Signature of Resident or Resident's Representative

Date

MGL ch. 201D: Health Care Agent authority to administer antipsychotics.

April, 2003 Department of Public Health Circular with Frequently Asked Questions Concerning the Use of Antipsychotic Medications in Long-term Care Facilities.



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617-753-8000

CIRCULAR LETTER: DHCQ 03-04-433

TO: Long Term Care Facility Administrators
FROM: Paul Dreyer, Ph.D., Director
DATE: April 4, 2003
SUBJECT: Frequently Asked Questions Concerning the Use of Antipsychotic Medications in Long-term Care Facilities.

Attached for your information is a series of questions and answers concerning the use of antipsychotic medications in Massachusetts's nursing homes. Please contact Donna Allen at 617-753-8106 or Sondra Korman at (617) 624-5220 if you have questions.

**FREQUENTLY ASKED QUESTIONS: TREATMENT OF LONG-TERM CARE FACILITY
RESIDENTS WITH ANTIPSYCHOTIC MEDICATIONS**

Introduction

Massachusetts's courts recognize a general right of all individuals to control medical treatment decisions, including the right to refuse medical treatment. This right extends to both competent as well as incompetent individuals. The laws governing the administration of anti-psychotic medications are designed to ensure that these legal principles are honored to the greatest extent possible.

Federal and state law governing long-term care facilities specifically prohibit the use of antipsychotic drug therapy for residents without the informed consent of the resident or appropriate legal decision-maker. Further, antipsychotic medication treatment may not be administered unless medically necessary to treat a specific condition and in accordance with a written treatment plan designed to discontinue the medications if possible. Consent to treatment is relatively easy to obtain when the resident is able to understand treatment choices and make an informed decision as to whether to accept antipsychotic medications. The difficult issues and potential legal problems arise when residents lack the ability to provide informed consent due to mental and/or physical impairments and facilities attempt to determine who, if anyone, is the appropriate legal decision-maker for the resident. The following outline addresses commonly asked questions and provides guidance to facilities in resolving these legal issues.

1. Can a resident's health care agent consent to treatment with antipsychotic medications?

Yes. In accordance with an Attorney General's informal opinion, the designated health care agent has the authority to make all health care decisions, including treatment with antipsychotic medications, without court intervention if:

- 1) the resident has signed a valid health care proxy;
- 2) the attending physician has determined that the resident lacks the capacity to make or communicate health care decisions, made an entry in the medical chart of that determination noting the cause and nature and extent and duration of the incapacity, and notified the agent, orally and in writing, of that determination;
- 3) the resident has not limited the agent's authority to consent to treatment with antipsychotic medications on the health care proxy form; and
- 4) the resident has not revoked or indicated a specific intent to revoke the health care proxy

Please note that a refusal to accept antipsychotic medication may indicate an intent to revoke the health care agent's authority. In such situations, the facility should take steps to obtain court authority to treat. See Question No. 5.

The following questions assume that a resident has not executed a valid health care proxy:

2. Under what circumstances can the facility administer antipsychotic medications to a resident if that resident has not been declared "incompetent" by a court of law?

The Attorney General's regulations governing long-term care facilities make it clear that the focus of the inquiry should be on the resident's ability to provide informed consent, not on whether the resident has been "adjudicated incompetent" by a court.

Case 1: If that resident has the ability to make an informed decision as to treatment with antipsychotic medication and the resident has consented to such treatment, the facility can administer antipsychotic medication to the resident in accordance with a written treatment plan.

Case 2: If a clinical determination has been made by a physician or psychiatrist that the resident lacks the ability to provide informed consent, the facility must take the necessary steps to seek court authority to treat with antipsychotic medication (even if the resident is accepting the medication).

3. Can a family member consent to treatment with antipsychotic medications on behalf of a resident who lacks decision-making capacity?

No. A specific probate court proceeding (commonly referred to as a Rogers hearing) is necessary before the facility may legally administer antipsychotic medication to an individual who lacks the ability to give informed consent. As more fully described above, court authority may not be required if the family member is the resident's health care agent. See Question No.1.

4. If the resident has a legal guardian, can the legal guardian consent to treatment with antipsychotic medications?

No. A legal guardian has the authority to consent to routine and customary (as opposed to extraordinary) medical decisions, including admissions to nursing homes and hospitals. In the 1983 Rogers v. Commissioner, Department of Mental Health decision, the Massachusetts Supreme Judicial Court ruled that the administration of antipsychotic medication is "extraordinary treatment" and that consent to such treatment can not be delegated to a resident's legal guardian. Rather, court authorization to treat with antipsychotic medications is required and typically, the court will direct the guardian to monitor such treatment ("the Rogers Monitor"). In order to determine what, if any, court action is required, the guardianship decree should be reviewed to determine whether the court has authorized treatment with antipsychotic medications.

5. How does a facility obtain specific court authority?

If a resident lacks the capacity to give informed consent and does not have a valid health care proxy, the facility must file a probate court guardianship petition seeking specific authorization to treat with antipsychotic medications. Generally, this request is combined with the initial guardianship petition. In cases where a guardian is already in place but there is no court order authorizing treatment with antipsychotic medications, the facility must seek such an order from the court through a General Petition.

The court appoints an attorney to represent the resident in this proceeding. After interested parties receive notice, the court holds a hearing to determine 1) whether the person is incompetent to make treatment decisions and, if so, 2) whether the individual would accept treatment with antipsychotic medications if he/she were competent to so choose (commonly referred to as the "substituted judgment" determination). The facility's physician is required to submit a proposed treatment plan and an affidavit which contains information on the substituted judgment factors: the expressed wishes of the resident; the resident's religious beliefs; the impact of the treatment on the resident's family; the side effects; the risks and benefits of the proposed treatment, and the prognosis with and without the treatment. If the evidence warrants treatment, the court will issue an order specifically authorizing the medical provider to treat the individual with antipsychotic medications in accordance with a written treatment plan. Generally, courts appoint the resident's legal guardian as the "monitor" of the treatment plan. The guardian/monitor has the responsibility to assess the usefulness of the treatment and may be required to report to the court regarding this treatment.

6. How long do treatment orders last?

Because the law views antipsychotic drug therapy as highly invasive treatment, each court-approved treatment order contains a court review date (generally on an annual basis) and an expiration

date. The facility must ensure that the treatment plan reviews are conducted in accordance with the court order. Additionally, the facility must request that the court amend the treatment plan if the medical provider determines that the resident requires an antipsychotic medication not listed as an alternative on the treatment plan.

SUMMARY

Antipsychotic medications may be administered in the following ways:

1. With the informed consent of the resident and in accordance with a written treatment plan; or
2. With the consent of a health care agent under the authority of a valid health care proxy; or
3. In accordance with a court-approved Rogers treatment plan, and appointment of a Rogers Monitor.

References:

Federal Law

42 CFR 483.10(a)(4)

42 CFR 483.75

42 CFR 483.25(l)(1)(2)

State Law

M.G.L.c. 201, §§6 et seq.

M.G.L.c. 201D, §§1 et seq.

105 CMR 150.002(A)(2) (Department of Public Health Licensing)

940 CMR 4.08(18)(19) (Consumer Protection--Governing Long-Term Care Facilities)

Case law

Rogers v. Commissioner of the Department of Mental Health, 390 Mass. 489, 458 N.E.2d 308 (1983)

Guardianship of Weedon, 409 Mass. 196, 565 N.E. 2d 432 (1991)

Letter from Barbara Anthony, Chief, Public Protection Bureau, Office of the Attorney General to Alex Moschella, Esq., July 24, 1997

Attorney General's 1997 Letter on LTC Facility Regs: 940 CMR 4.08 (18)(19)



SCOTT HARSHBARGER
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July 24, 1997

Alex L. Moschella, Esq.
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Somerville, MA 02144

Dear Attorney Moschella:

This letter is in response to the question raised at the National Academy of Elder Law Attorneys Massachusetts Chapter program in April regarding whether, under Rogers v. Commissioner of the Department of Mental Health, the caretaker of an incompetent patient is required to obtain a court order prior to administering prescribed antipsychotic medication, even if: (1) the incompetent patient had previously appointed an authorized health care agent pursuant to G. L. c. 201D [The Health Care Proxy Act]; (2) the agent has consented to the medication on the patient's behalf; and (3) the patient has not objected to or refused the medication. It is our understanding that there has been some confusion among the elder law practitioners as to how to interpret the Attorney General's long term care facility regulations 940 CMR 4.08 (18) and (19), when this issue arises. While this letter does not serve as a formal published opinion of the Attorney General, which may only be issued pursuant to specific statutory authority not applicable here, in the interest of addressing a matter of significant concern to elders and long term health care providers, we offer the following informal clarification.

in Rogers, the Supreme Judicial Court held that before antipsychotic drugs could be administered to an incompetent patient, counsel and a guardian must be appointed for the patient and the court must then determine what the incompetent patient's desires would have been, had he or she been competent to consent on his or her own behalf. If the court determines the patient would have consented to the medication, the court is required to establish a treatment plan and a treatment-monitoring mechanism as well. The underlying purpose of a Rogers hearing is to protect incompetent patients

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from forcible treatment in circumstances where the patient would refuse the treatment were he or she competent to do so.

As you know, the Legislature enacted the Health Care Proxy Act seven years after the Rogers decision as a way of providing individuals with the means for maintaining control over medical decision-making in the event that they should become incapacitated. In cases involving a validly executed health care proxy, the person selects a substitute decision maker who is thereby legally authorized to represent the principal's own health care decision-making rights. The statute lays out specific requirements that must be fulfilled before a health care agent can exercise his or her authority on behalf of the patient. Specifically, the law requires that the health care agent must consult with all of the principal's health care providers and must fully consider all acceptable medical alternatives regarding the principal's diagnosis, treatment and side effects. M.G.L. c. 201D, § 5. The law also requires that the agent consider the principal's wishes, if known – including the principal's religious and moral beliefs – or, if the principal's wishes are unknown, in accordance with the agent's assessment of the principal's best interests. Id. Under the law, every person has the right to exercise informed consent and appoint a health care agent by executing a valid health care proxy while he or she is competent. Moreover, a principal may revoke a health care proxy at any time by any act evidencing a specific intent to revoke the proxy.

We believe Chapter 201D, in all significant respects, establishes standards that are consistent with the Rogers requirements for both informed consent by the patient and for substitution of judgment by the health care agent. As set forth in Rogers, the factors to be considered by a judge in determining whether a judicial "substituted judgment" decision is required include: (1) the patient's expressed preferences regarding treatment; (2) the strength of the patient's religious convictions; (3) the impact of the decision on the patient's family; (4) the probability of adverse side effects; (5) the patient's prognosis without treatment; (6) the patient's prognosis with treatment; and (7) any other factors which appear relevant to the determination. 390 Mass. at 505-506. These factors coincide with the requirements that a health care proxy agent must consider in making health care decisions for a principal pursuant to the Health Care

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Proxy Act. M.G.L. c. 201D, §§ 5 and 6. Because a decision made by an authorized health care agent provides the patient with the same type of protection a Rogers hearing is designed to provide, we conclude that an authorized health care agent may consent on behalf of an incompetent patient to the administration of antipsychotic medication without a Rogers hearing.

We note that, in the Attorney General's view, a consent to antipsychotic drugs on behalf of an incompetent patient made by an authorized health care agent will only eliminate the need for a Rogers hearing if the patient does not in any way indicate a contrary decision. When a patient refuses or objects to the administration of antipsychotic medications, we believe that a court-ordered substituted judgment is required, whether or not the patient has a valid health care proxy. M.G.L. c. 201D, § 7, permits the principal to revoke his or her proxy "by notifying the agent or a health care provider orally or in writing or by any other act evidencing a specific intent to revoke the proxy." Refusal to accept medication may be deemed a revocation of the proxy and would, therefore, void any consent previously given by the agent. Moreover, an incompetent patient without a health care proxy always requires a Rogers hearing, regardless of whether the patient will accept the proffered medication, because he or she is incapable of giving consent and has not previously designated a proxy to do so on his or her behalf.

I hope that this letter offers some assistance in your work. The intent of the Attorney General's long term care regulations is to protect patients covered by Rogers. However, we see no benefit to patients in interpreting the regulations in a way that both effectively deprives an incompetent patient of his or her right to have an authorized health agent chosen by the patient make decisions on the patient's behalf and imposes delay and expense on an incompetent patient without adding any protection to the patient's interests.

In light of this letter, the Attorney General would be very interested in working further with the private bar to (1) encourage the use of health care proxies, especially prior to nursing home admissions; (2) educate the general public about the specific

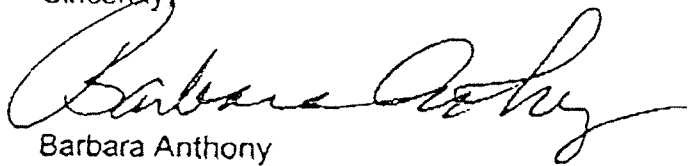
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issues raised by Rogers and the use of antipsychotic drugs; and (3) ensure compliance with the long term care facility regulations. Please do not hesitate to contact me at the number below if you wish to discuss this matter further. Thank you.

Sincerely,



Barbara Anthony
Assistant Attorney General
Chief, Public Protection Bureau
(617) 727-2200, ext. 2925

cc: Kenneth A. Behar, Esq., Behar & Kalman
Robert D. Fleischner, Esq., Center for Public Representation
John J. Ford, Esq., Neighborhood Legal Services
Wynn Gerhard, Esq., Greater Boston Legal Services
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Alan S. Goldberg, Esq., Goulston & Storrs
Mary McKenna, Executive Office of Elder Affairs
Gwen O'Sullivan, Esq., Department of Public Health
Scott Plumb, Massachusetts Extended Care Federation
Deborah Thomson, Alzheimer's Association

Should your client restrict or limit their Health Care Agent's authority?

The Health Care Proxy form commonly used in Massachusetts includes a section where clients can list exceptions to the authority granted to a Health Care Agent.

Disability Rights of California has prepared an Advance Directive Completion Checklist and an Individual Health Care Instruction Worksheet that lists topics of concern that clients may want to consider.

http://www.disabilityrightsca.org/pubs/540701.htm#_Toc122837747

This worksheet is intended to help clients complete the Advance Health Care Directive form, with questions to help think through some of the decisions you may want to make about your physical and mental health treatment.



Among the topics are: *Medications*. The client could be asked:

1. What are the medications you are currently taking? How often? At what dosages?
2. Do you want to take medication in the hospital? ----- Yes / No
3. What kinds of medication would you prefer if you were hospitalized? Which medications? At what dosages?
4. Are there medications you would not want under any circumstances?
5. What time of day do you prefer to take medication?

But, query: what if antipsychotic medications would benefit a patient who had listed antipsychotics among the medications he/she would not want under any circumstances? Would the listing of specific exceptions force the client/patient into costly and otherwise unnecessary Probate Court proceedings? Does this possibility suggest that the Agent be given general authority without exceptions, so that decisions can be based on what the person would have wanted under the circumstances?

The Alternative to drugging memory loss patients: understand the Symptoms of Memory Loss, and how to respond.

Attorneys who are familiar with stages of memory loss can help families avoid the need for drugs, and better advocate for the client/incapacitated person when filing Rogers guardianships or amending Rogers Orders/treatment plans.

STAGE 1 – EARLY



SYMPTOMS and EXAMPLES

Recent memory loss affects performance: Forgets grocery list, May get lost

Vague complaints: Headache when forgets, “Something is wrong”, “I’m going crazy”

Less tolerant/angry: Upset with family visits, Cannot tolerate children

Less energy: Frequent naps, Sighs often

No initiative: cannot self start, Seems disinterested

No longer does routine tasks: cooking

Slow to learn/react: May not respond to question or request, Forgets what is just told, Asks, “What was I doing again?”

Loss of spontaneity or zest: Seems apathetic or down in the dumps, Seems less outgoing

Mood/personality change: Does not seem like himself

Takes longer with tasks: Especially ADLs, Difficulty following recipes

Poor judgment, Makes poor decision driving, Leaves the stove on

Difficulty with money and calculation: Does not pay bills, Pays bills twice

May become suspicious or paranoid; Accuses people of taking things, Calls the police

Difficulty thinking abstract thoughts: Cannot interpret proverbs, Difficulty balancing the checkbook

STAGE 2 – MIDDLE



SYMPTOMS and EXAMPLES

Needs assistance in many areas: Needs help bathing, Needs help with eating

Difficulty understanding, planning, concentrating, deciding; becomes lost in conversation

Cannot follow through on tasks

Becomes frustrated with choices

Slow to react or overreacts: May look faraway when spoken to

Becomes angry with simple request

Unable to cope with failure Feels hopeless when makes mistakes

Self-absorbed, Lacks empathy

Increased memory loss and confusion, May not recognize family members
 Communication greatly impaired
 Difficulty organizing thoughts: Talks nonsense, Uses made up words
 Has trouble expressing needs: May not be able to state when in pain
 May begin to wander: Looks for something familiar; Disoriented to time/place/self; May not be aware of where is living
 May think it is a different year
 May think is much younger than actual age
 Inappropriate behavior: Wears 3 shirts at once
 Unable to recognize familiar: May wish to go home when already at home
 Repetitive statements or movements: Repeats questions consistently
 Perception/motor difficulties: Difficulty sitting on a chair, Steps over change in flooring pattern
 Less impulse control: Swears, Hits others
 Delusions and hallucinations: Believes he/she is still employed, Sees things that are not there

STAGE 3 – LATE



SYMPTOMS and EXAMPLES

Needs assistance in many areas: Needs help bathing, Needs help with eating
 Difficulty understanding, planning, concentrating, deciding:
 Becomes lost in conversation
 Cannot follow through on tasks
 Becomes frustrated with choices
 Slow to react or overreacts: May look faraway when spoken to
 Becomes angry with simple request: Unable to cope with failure,
 Feels hopeless when makes mistakes
 Self-absorbed: Lacks empathy

Increased memory loss and confusion: May not recognize family members
 Communication greatly impaired
 Difficulty organizing thoughts: Talks nonsense, Uses made up words
 Has trouble expressing needs: May not be able to state when in pain
 May begin to wander: Looks for something familiar, Disoriented to time/place/self, May not be aware of where is living
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