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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

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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.

If you have any questions about the Schedule of Psychotropic Medications please contact the Bureau of Health Care Safety and Quality, Office of Prescription Monitoring and Drug Control, at jonathan.mundy@state.ma.us.

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)

**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)
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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