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CIRCULAR LETTER 17-2-699

TO: Long-Term Care Facility Administrators

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

James Lavery, J.D., Director, Bureau of Health Professions Licensure

DATE: February 1, 2017

SUBJECT: **REVISED** Informed Written Consent for Use of Psychotropic Medications in Long-Term Care Facilities.

The purpose of this letter is to revise, update and replace the policies and guidance published in the February 1, 2016 Circular Letter: [DHCQ 16-2-653](#).

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 psychotropic medications (Attachment A) 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.*

As indicated in subsection (c) above, informed written consent must be obtained prior to administration using the Department's form at Attachment B, below. Written consent can be obtained in person, by fax or by means of a scanned and emailed copy of the consent form. Verbal consent by telephone, even if witnessed by a second staff member of the facility, does not constitute written consent.

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 (See Attachment A);
2. Appropriate training of staff regarding the requirements of *Rogers v. Commissioner of the Department of Mental Health*, 390 Mass. 489 (1983) (discussed below), including the acknowledgment that, consistent with *Rogers*, guardians may not consent to the administration of antipsychotic medications.

Documenting Informed Consent

In order to meet Section 72BB's requirements for documenting informed consent, prior to the administration of any drug included on Attachment A, long term care facilities must complete the Department's prescribed form (Attachment B), and prior to or upon administration, include the completed form in the resident's medical record. In order to complete the form, the drug's prescriber must discuss the following with the resident or the resident's legal representative:

- (i) the purpose for administering the psychotropic drug listed on Attachment A;
- (ii) the prescribed dosage; and
- (iii) any known effect or side effect of the psychotropic medication.
 - a. A separate document with this information may be attached to the form, provided that each attached page is numbered (e.g. 2 of 5), initialed by the resident or the resident's legal representative, and dated contemporaneously with the form itself.
 - b. Printer-friendly versions of package inserts for FDA-approved drugs can be found [here](https://medlineplus.gov/druginformation.html): <https://medlineplus.gov/druginformation.html>.

The discussion between the prescriber and the resident or the resident's legal representative may take place by phone. A facility representative must then document this discussion by completing the form, including all necessary signatures within a reasonably proximate time period, so as not to negate informed consent.

While prescribers are not required to complete this process each and every time a resident is administered a dose of psychotropic medication, written informed consent must be obtained each time a new or renewed prescription falls outside the dosage to which the resident or the resident's legal representative previously consented, or once a year, whichever is shorter. In the event that the medication will continue to be administered in the following year without a change in dosage, the facility may re-use the form so

long as the prescriber explains again the risks and benefits to the resident or his or her legal representative, and the facility representative updates the signatures and dates, the date of discussion with the prescriber, and facility representative information. If all relevant information is identical, written informed consent may be renewed using the previously signed form by attaching a notice of renewal to the updated form. The notice and any additional attachments must include all necessary attestations and signatures that are on the original form, updated discussion dates, and updated names of prescriber and facility representative, as necessary. Each page of the notice and any additional attachments must be re-initialed, dated and numbered to precisely indicate the relative page number (e.g. 2 of 4, etc.).

Written informed consent may be withdrawn, either verbally or in writing, at any time. Withdrawal of consent must be documented in the patient record. If a resident withdraws consent for a medication on Attachment A, the medication may not be administered without the facility obtaining written informed consent, as if for the first time.

Certain controlled substances that are not listed on Attachment A are sometimes used in the treatment of a psychiatric diagnosis, symptom, or behavior. This includes, but is not limited to, certain medications used to treat seizure disorders, certain beta blockers, and other controlled substances. When any of these controlled substances or any other medication is used to treat a psychiatric diagnosis, symptom, or behavior, the facility shall obtain informed written consent prior to administering the medication to a resident. In order to determine whether a facility must obtain written informed consent prior to administering a controlled substance that is not listed on Attachment A, the facility should consider the circumstances that led to the order, including the resident's symptoms and any behaviors, and refer to the prescriber's order to determine the indication for use of the controlled substance.

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 HCP is activated by a physician after determining that the resident lacks capacity;
- (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.

Emergency Administration

A facility may administer a medication listed on Attachment A without prior informed written consent to treat a resident only when:

1. a resident poses an imminent threat of harm to himself or others, and there is no clinically appropriate alternative to psychotropic drugs, including behavioral interventions; or
2. in rare circumstances, even when no threat of violence exists, to prevent the "immediate, substantial, and irreversible deterioration of a serious medical condition" in cases in which "even the smallest of avoidable delays would be intolerable." See *Guardianship of Roe*, 383 Mass. 415, 441.

A facility shall engage in continued evaluation of emergency need and shall obtain informed written consent as soon as practicable, but no later than three calendar days, following emergency administration of a psychotropic medication. Emergency administration and subsequent consent shall be documented in the medical record.

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 Office of Prescription Monitoring and Drug Control at dcp.dph@state.ma.us.

Attachment A
Schedule of Psychotropic Drugs
(Updated July, 2016)

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

Prior to administering any drug listed on this schedule to a resident of a long-term care facility, the facility shall obtain informed written consent as required by M.G.L. c. 111, section 72BB. **Documentation of Informed Consent is also 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 3 of Circular Letter 17-2-699, above)

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 (Trintellix)

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, Fazacllo, 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/fluoxetine (Symbyax)
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 July, 2016)

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)

Mood Stabilizer

lithium (Lithobid, Eskalith)

Miscellaneous Drugs

atomoxetine (Strattera)
clomipramine (Anafranil)
clonidine ER (Kapvay)
fluvoxamine (Luvox)
guanfacine (Tenex)
guanfacine ER (Intuniv)
reserpine (Serpasil)
naltrexone (ReVia)

Attachment B
Informed Consent for Psychotropic Administration Form
 This consent form shall be kept in the resident's medical record.

| | |
|-----------------|-----------------------------------|
| [Facility Name] | [Affix resident information here] |
|-----------------|-----------------------------------|

| | |
|--|--|
| Name of Resident | |
| Date/Time of Discussion with Prescriber | |
| Prescriber Name | |
| Facility Representative Name/Title | |
| Name of Medication Proposed/Prescribed (Only one medication per form) | |
| Dose, Range, and Frequency | |
| How Administered | |
| 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 legal representative refused consent.

By checking here and by my signature below, I give consent for the above named medication and anticipated dosage. My signature also indicates that I understand the above listed risks and benefits of the medication.

If the proposed medication is an anti-psychotic, and the resident has a guardian, evidence of *Rogers* substituted judgment is required.

By checking here and by my signature below, I attest that I am a guardian with substituted judgment authority and the *Rogers* monitor has been informed and authorized this medication.

Signature of Resident or Resident's Legal Representative

Date

Signature of Facility Representative

Date