

NEW YORK STATE DEPARTMENT OF HEALTH

CERTIFIED MEDICAL RESPITE PROGRAM

Guidance on Medication

The Department of Health (Department) adopted new regulations at **10 New York Codes, Rules and Regulations (NYCRR) §1007.12** that establish requirements for medication storage and handling in certified medical respite programs. This guidance document is intended to articulate policy pursuant to the Department’s regulations. **Each medical respite program must establish a policy (or policies) that addresses medication storage and disposal and complies with all applicable federal, state, and local laws, ordinances, rules, and regulations and this guidance.**

OVERVIEW

In accordance with 10 NYCRR §1007.12(e)(14), certified medical respite programs must provide recipients with a means to safely store and secure medications, including medications that require refrigeration. **Note that certified medical respite programs are *not* qualified to hold medications on behalf of recipients or administer medications to recipients.**

- For the purposes of this guidance, *hold medications* means to take possession of, including to store, a recipient’s medications in such a way as to remove physical control of the medications from the recipient.
 - Storing recipient medications that require refrigeration in a shared secure refrigerator does *not* constitute holding medications on behalf of recipients, even if the arrangement is such that recipients require staff assistance to access the refrigerator, as long as the medical respite program commits to providing this assistance on demand, 24 hours a day, 7 days a week (see page 3 of this guidance for more information).
- For the purposes of this guidance, *administer medications* means to apply medications to a recipient by injection, inhalation, ingestion, or any other means, or to direct a recipient through the process of applying medications to themselves or another person.
 - Offering a self-directing recipient purely physical support (e.g., opening a blister pack at the recipient’s request) or general verbal reminders (e.g., “Did you remember to take your medications this morning?”) does *not* constitute administration of medications.

ROOM TEMPERATURE STORAGE

For prescription and non-prescription medications that can be stored at room temperature, medical respite programs must inform recipients of their responsibility to safeguard their own medications against loss or diversion. Accordingly, recipients must:

- Store medications in their assigned secure locker; or

- If the recipient has a single occupancy sleeping area with a locking door, store medications in their assigned secure sleeping area; or
- Hold medications on their person.

Additionally, the medical respite program must advise all program recipients that sharing of prescription and non-prescription medications is strictly prohibited within the medical respite program.

COLD STORAGE

For prescription and non-prescription medications that require cold storage, medical respite programs must provide recipients access to a refrigerator that is secure and appropriate for storing pharmaceuticals.

Option 1

The medical respite program may keep a small stock of compact (“mini”) refrigerators to be installed in individual recipients’ sleeping areas on an as-needed basis. Such refrigerators must have:

- Refrigerator functionality *only* (i.e., the unit must *not* include a freezer compartment or freezer drawer);
- Digital temperature control and a built-in digital temperature display;
- Demonstrated capacity to maintain temperatures between 36°F-46°F (2°C-8°C) or the temperature range specified by a particular medication’s manufacturer;
- An external **combination lock** (see page 3 of this guidance for more information) to secure the refrigerator door; and
- A mechanism to prevent unauthorized removal of the refrigerator from the sleeping area (e.g., locking the refrigerator to a permanent fixture on the wall or floor).

Additionally, the recipient must agree to use the refrigerator exclusively for medication storage (i.e., no food or beverages allowed) to prevent unnecessary fluctuations in temperature. For more information about setting up and maintaining a refrigerator that will be used to store pharmaceuticals, see the CDC’s [Vaccine Storage and Handling Toolkit](#).

If two recipients who share a sleeping area both need cold storage for prescription medications, the medical respite program must provide each recipient with their own secure refrigerator or otherwise ensure that each recipient has access only to their own medications (e.g., by permanently installing individual lockboxes, each outfitted with a **combination lock**, in the shared compact refrigerator).

Option 2

The medical respite program may designate a communal full-size refrigerator to be used exclusively for secure medication storage. If the medical respite program selects Option 2, the refrigerator must:

- Have its door secured with a lock *or* be located in a secure (i.e., lockable) room; *and*

- Weigh at least 750 pounds *or* be bolted to the floor or wall to prevent unauthorized removal from the facility.

Additionally, the refrigerator must have permanently installed lockboxes (or another type of secure, immovable compartment), each outfitted with a **combination lock**, that can be individually assigned to program recipients who require refrigerated storage of their medications.

The refrigerator must also be:

- Continuously monitored with a temperature monitoring device (built-in or external) that has a digital display;
- Capable of maintaining temperatures between 36°F-46°F (2°C-8°C); and
- Used exclusively for medication storage (i.e., no food or beverages allowed).

*For information about setting up a refrigerator that will be used to store pharmaceuticals, see the [Vaccine Storage and Handling Toolkit](#).

Unless qualified to administer medications to recipients in compliance with all applicable federal, state, and local laws, ordinances, rules, and regulations, medical respite program staff may *only* unlock or otherwise provide access to the communal refrigerator in which a recipient's medications are stored. The recipient or an appropriately qualified individual (e.g., the recipient's home health services provider) must be responsible for selecting the correct medication from the recipient's assigned storage box and ensuring the medication is taken in accordance with the prescribing provider's instructions.

Medical respite programs must allow recipients access to all of their medications, including refrigerated medications, 24 hours a day, 7 days a week. To streamline operations, medical respite programs may offer recipients standard times when a dedicated staff person will be readily available to facilitate retrieval of refrigerated medications (e.g., at meals, before bed). However, the medical respite program must *also* be prepared to provide on-demand assistance to recipients who wish to retrieve their refrigerated medications at any time of day or night.

ALLOWABLE LOCK SYSTEMS

Where this guidance specifies that a **combination lock** must be used, the medical respite program must select a combination lock with a push-button mechanism; combination locks with a dial or wheel mechanism are *not* allowable. Additionally, the medical respite program should select a "reprogrammable" model, so the combination can be changed any time a lock is assigned to a new recipient or the combination to an assigned lock is compromised. Recipients should be permitted to choose the combination for their assigned lock and must be advised against sharing this combination with other program recipients or staff.

Where this guidance does *not* specify that a combination lock must be used, the medical respite program may select any reliable lock system (e.g., combination lock, traditional metal key, electronic access card, biometric security) that suits program needs. Note, however, that combination locks with a

dial or wheel mechanism are never allowable. The medical respite program must evaluate the selected lock system(s) for security vulnerabilities (e.g., unauthorized copying of metal keys, theft or loss of electronic access cards) and take reasonable measures to mitigate these vulnerabilities.

SELF-INJECTED MEDICATIONS

Recipients who are prescribed self-injected medications must:

- Be advised of their responsibility to securely store all needles and related equipment (as described on pages 1-2 of this guidance);
- Be given access to a clean, sanitary space for self-administration of the injectable medication; and
- Be given a safe needle disposal box.

The medical respite program (or its contractor) must:

- Check recipients' needle disposal boxes regularly to ensure that they do not become overly full;
- Safely remove full need disposal boxes from the facility; and
- Promptly provide recipients with replacement needle disposal boxes.

NON-PRESCRIPTION MEDICATIONS

If the medical respite program **chooses** to maintain a stock supply of nonprescription over-the-counter medications for recipients to self-administer, the medical respite program must:

- Establish a system for monitoring inventory and tracking which program staff and recipients have accessed the stock supply; and
- Monitor any expiration dates on the stock supply and discard those medications that have expired.

MEDICATION DISPOSAL

Unless qualified to hold recipient medications in compliance with all applicable federal, state, and local laws, ordinances, rules, and regulations, the medical respite program *cannot* legally take possession of prescription medications for the purpose of disposal. Instead, the medical respite program must be prepared to advise individual recipients on [safe disposal of unused medications](#). The medical respite program must also establish an internal procedure for handling any prescription medications left behind by recipients who have been discharged. The procedure should include steps for securely storing the unused medications, contacting the recipient to attempt return of the medications and, if return is not possible, contacting local law enforcement for further direction. The procedure must also establish a means of tracking the following information for each medication to be disposed of:

- Recipient's name;

- Name of medication;
- Amount discarded;
- Attempts to reach the recipient to arrange return of the medication; and
- Name or initials of staff person documenting this information.

MEDICATION RECORDS

Information on each recipient's medication regimen must be retained on file in a manner that assures both recipient privacy and accessibility for assistance in case of an emergency. The following information must be maintained for each recipient:

- The recipient's name;
- Identification of each medication;
- The current dosage, frequency, time, and route of each medication;
- The physician's name for each prescribed medication;
- The dates of each prescription change;
- Any contraindications noted by the physician; and
- The type of supervision and assistance, if any, needed by the recipient.

In accordance with §1007.14(f)(2), all recipient records, including medication information, must be retained by the medical respite program for at least 6 years after the recipient's discharge or death.

RECIPIENT ATTESTATION

The medical respite program must provide **all** recipients (and their representative or guardian, if a recipient is not self-directing) with written rules and procedures regarding medication storage and handling in the program facility. The rules and procedures must be written in plain language, and the medical respite program must make reasonable accommodations as needed for individuals who have limited English proficiency, limited literacy, or a disability (e.g., impaired vision) that interferes with the individual's ability to read and understand the rules and procedures. In addition to information specific to each medical respite program, these rules and procedures must clearly state that:

- The recipient (or their representative or guardian, if a recipient is not self-directing) has primary responsibility for protecting their medications from loss or diversion; and
- The recipient (and their representative or guardian, if a recipient is not self-directing) must never share their prescription or non-prescription medications with other program recipients.

The medical respite program must have **all** recipients (and their representative or guardian, if a recipient is not self-directing) sign the rules and procedures or otherwise attest that they received and understand the rules and procedures. The medical respite program must provide the recipient (and their representative or guardian, if a recipient is not self-directing) with a hard or electronic copy of the signed rules and procedures and retain a copy in the recipient's file.