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OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS OF THE STATE OF NEW YORK
TITLE 14. DEPARTMENT OF MENTAL HYGIENE
CHAPTER XIV. OFFICE FOR PEOPLE WITH DEVELOPMENTAL DISABILITIES
PART 633. PROTECTION OF INDIVIDUALS RECEIVING SERVICES IN FACILITIES OPERATED
AND/OR CERTIFIED BY OMRDD

Current through July 31, 2012

* Section 633.17.* Medication (including vitamins).

(a) Principles of compliance.

(1) The management and administration of medication (see glossary) shall take place in the safest possible manner, while at the same time enabling facilities to access the services of health care professionals (see glossary) and pharmacists in the community without imposing undue or unenforceable requirements on such parties or the facility itself. However, the very fact that a person (see glossary) who is developmentally disabled is entrusted to the care and supervision of a facility (see glossary) operated or certified by OMRDD means that certain precautions must be taken and certain procedures observed that might not be considered necessary in a familial home environment.

(2) Adherence to this section shall be required of all residential facilities after January 1, 1990.

(3) After January 1, 1990, adherence to this section shall be required of any nonresidential facility that is responsible for the administration of medication while a person is in attendance. For those nonresidential facilities which are not required, by regulation, to be responsible for the administration of medication and whose governing body has adopted a policy not to administer medication, the following shall apply:

(i) There is written policy/procedure to this effect.

(ii) There is written policy/procedure as to the responsibilities of persons in attendance, and/or those where such persons reside, to ensure the administration of medication, should it become necessary (e.g., the person in attendance will be responsible for self-administration of medication [see glossary] and therefore must be capable of independent self-administration of medication; arrangements are made for someone from a person's place of residence to administer medication or supervise or assist in the self-administration of medication).

(iii) The above policies/procedure are conveyed to applicants, persons in attendance, parents, guardians or correspondents in conformance with section 633.4(a)(7) of this Part.

(iv) The facility periodically assesses its policy relative to the needs of persons currently served.

(4) This section applies to the management and administration of medication to individuals (see glossary) while in a facility or while under the facility's direct supervision.

(5) Each agency/facility shall develop its own policies/procedures relative to prescribed (see glossary) and over-the-counter medication (see glossary) as is relevant to its needs. Family care homes shall adhere to policies/procedures as developed by their sponsoring agency. All such policies/procedures shall be in conformance with this Part. ICF/DD's shall also ensure compliance with Part 681.

(6) This section does not address the requirements to be met by a pharmacy located in a facility.

(7) All medication shall be prescribed or ordered, obtained, provided, received, administered,

safeguarded, documented, refilled and/or disposed of in a manner that ensures the health, safety, and well-being of the people being served and in conformance with all applicable Federal and State statute or regulations. Where requirements are more restrictive in Part 681 (for ICF/DD's), they shall be controlling.

(8) Every person has the right to be free from the unnecessary use of medication.

(9) Every effort shall be made to ensure that medication is prescribed or ordered in the lowest dosage possible to achieve the desired effect(s).

(10) No medication shall be used for the convenience of staff or as a substitute for programming.

(11) Special attention shall be given to those individuals receiving psychotropic medication to detect and prevent possible medical problems.

(12) Medication purchased with an individual's own personal funds shall be used by or for that person only. A facility may purchase an over-the-counter medication for use by more than one person.

(13) The use of over-the-counter medication is permitted when administered in accordance with the following to ensure that the medication is appropriate and that there will be no expected contraindications:

(i) Approval for a specific individual to use or be administered a medication is received in writing on no less than an annual basis (but in conformance with any other facility specific controlling regulations) from that individual's practitioner(s) (see glossary).

(ii) There is information in an individual's record, and available to staff or the family care provider, as to the condition for which a medication is to be used, the dosage, the frequency with which it may be administered, and any specific instructions related to the medication.

(iii) Administration of an over-the-counter medication does not exceed two days unless so specified by a practitioner; or the practitioner is contacted for instructions for extended use. Exceptions are certain vitamins and over-the-counter medications that a practitioner instructs to be given on a daily basis.

(iv) Nothing in this section shall prevent a person residing in a supportive community residence or a family care home, who is capable of independent self-administration of medication, from obtaining and using over-the-counter medication at his or her discretion. However, the individual shall be given appropriate guidance relative to obtaining and self-administering over-the-counter medications.

(14) Administration of prescribed and over-the-counter medication shall be in conformance with the following:

(i) A prescribed medication shall be administered only to the person for whom it is prescribed, and in compliance with the prescribing practitioner's instructions.

(ii) If there is a significant adverse reaction, a significant change in behavior, or any other significant indication(s) of a problem that may be related to a medication currently being administered to or by an individual, the use of the medication is to be suspended. The indicated problem is to be reported to the prescribing practitioner immediately. If the prescribing practitioner is not available, medical treatment is to be obtained elsewhere, if indicated. However, the prescribing practitioner shall receive notification as soon as possible of all adverse reactions, behavior changes, etc., that may be related to a medication administered to or by an individual, and any treatment received for the adverse reaction.

(iii) Medication shall be self-administered or administered only by the following:

(a) a person capable of independent self-administration of medication;

(b) a health care professional (a physician, dentist, physician's assistant, registered nurse, or licensed practical nurse holding current New York State licensure);

(c) staff (see glossary) providing direct care services (see glossary), as documented by job description, who have:

(1) successfully completed an OMRDD approved training course in medication; and

(2) successfully completed the required practicum; and

(3) been certified or recertified within the year to administer medication; or

(d) a family care provider whose name appears on the operating certificate for the family care home, and who has received training in medication administration in conformance with an OMRDD approved curriculum; or a sponsoring agency approved substitute, in the absence of the family care provider.

(iv) Nothing in this section shall prevent a person residing in a supportive community residence or a family care home, who is capable of independent self-administration of medication, from obtaining and using prescribed and/or over-the-counter medications. However, the individual shall be given appropriate guidance relative to obtaining and self-administering medications.

(15) Supervision and monitoring of staff.

(i) Medical or nursing supervision of those staff responsible for administering medication shall be

provided.

(ii) Supervision and monitoring shall be in accordance with agency/facility policies/procedures.

(16) Evaluation of persons for self-administration of medication (see glossary).

(i) If, upon admission, a person has not been evaluated as to his or her ability to self-administer medication, staff or the family care provider are responsible for the administration of medication.

(ii) Each person at a residential facility is to be evaluated by a program planning team (with input from a registered nurse, physician, or physician's assistant) at the first case review, but no later than three months after admission, to determine his or her current ability to self-administer medication. Other providers of services to the person, and his or her physician, shall be informed of the person's designation. A nonresidential facility that assumes responsibility for the administration of medication while a person is in attendance shall:

(a) accept the determination made at a person's place of residence in accordance with subparagraph (ii) of this paragraph, if the facility is OMRDD operated or certified; or

(b) evaluate the person; and

(c) evaluate all persons' who do not reside in an OMRDD operated or certified facility.

(iii) Evaluations shall be part of each person's plan of services and shall designate whether the person is:

(a) capable of independent self-administration of medication; or

(b) capable of self-administration of medication with supervision; or

(c) capable of self-administration of medication with assistance; or

(d) incapable of self-administration of medication (administration of medication must be done by others).

(iv) Evaluations shall be reviewed no less than annually and may be incorporated into the program planning review process.

(v) For a person who is not capable of independent self-administration of medication, a plan shall be developed by his or her program planning team. A nonresidential facility that assumes the responsibility for the administration of medication, shall assume this obligation for those persons not residing in an OMRDD operated or certified facility. The purpose of the plan is to assist the person to ultimately reach his or her optimum level of capability in the self-administration of medication, unless:

(a) the program planning team determines that other programmatic needs are of greater priority and are to be addressed first; or

(b) the program planning team determines that such a plan is not appropriate; or

(c) a physician determines that a plan should not be developed for the person, and the program planning team concurs.

All such determinations, and the justification, shall be documented in each person's plan of services.

(vi) The method used to verify a person's level of self-administration and the documentation required shall be determined by agency/facility policy/procedures.

(vii) When a person, designated as capable of independent self-administration of medication, must be frequently reminded to take his or her medication, or there are other indications of lessening of skills related to self-administration, there shall be a reevaluation of the person's ability and a decision made as to whether the degree of supervision or assistance is to be increased.

(17) Records.

(i) Except as provided for in subparagraph (ii) of this paragraph, there shall be a separate record for the administration of medication for each person receiving medication. The record documenting administration shall specify at least the following:

(a) name of person receiving the medication;

(b) name of medication, dosage, and route of administration;

(c) time and date of administration; and

(d) signature of the party who supervised, assisted, administered, or independently self-administered the medication (or initials that correspond to those on a signature sheet).

(ii) In supportive community residences and family care homes:

(a) there shall be documentation as described in subparagraph (i) of this paragraph; or

(b) for persons who are capable of independent self-administration there shall be documentation in the person's clinical record of the supervision provided to ensure that the person is taking medication as required. Such supervision may be in the form of occasional verbal checks, checks on the amount of medication remaining, or in any manner or frequency deemed appropriate by the program planning team.

(iii) For the safety of the people residing in or attending a facility and as a support to those staff who have medication administration related responsibilities, there shall be information specific to each person on all medications to be administered to that person while at or under the supervision of the facility and its staff. The sponsoring agency shall ensure maintenance of this information for

people in family care homes and provide the information to the family care provider. For each medication a person is taking, this information shall include:

- (a) name of person taking the medication;
- (b) name of medication;
- (c) directions with regard to correct dose, form, method/route of administration, time of administration;
- (d) start and stop dates, if applicable;
- (e) expected therapeutic effects for the person taking the medication;
- (f) possible side effects to the person taking the medication; and
- (g) name of prescribing, ordering or approving practitioner.

(18) Medication regimen review.

(i) Residential facilities shall ensure that a review of a person's medication regimen is conducted on no less than a semi-annual basis. The review shall be made by a registered nurse, physician, physician's assistant, or pharmacist.

(ii) The medication regimen review shall include, at a minimum:

(a) A review of the person's medication record for potential adverse reactions, allergies, interactions, contraindications, or irregularities; related laboratory work shall be included in this review.

(b) An assessment of the person's response to medication therapy to determine if the medication is achieving the stated objectives established by the prescribing practitioner.

(c) Recommendations to the primary and/or consulting practitioner of any indicated changes in the person's medication regimen.

(d) Determination of the need for a more frequent review depending upon the person's medical status.

(e) Documentation of the review, findings, and any recommendations made.

(19) Storage of medication at the facility.

(i) Medication shall be maintained in the original container in which it was received. All containers shall be labeled. Labels shall be clear and legible.

(ii) Safe, secure, appropriate, and adequate storage space shall be provided.

(a) Other than in a supportive community residence or a family care home, medication shall be kept in a secure, locked storage area.

(b) Persons who are capable of independent self-administration of medication may have their medication stored so as to be personally accessible to themselves and staff who are currently certified to administer medication, those who are health care professionals and family care providers, or their substitutes, if such a procedure does not expose other residents to harm.

(c) Other than in a supportive community residence or a family care home, medication stored in a refrigerator containing food shall be placed in a separate locked container clearly marked to indicate that it contains medication.

(d) Other than in a supportive community residence a family care home, or as specified in clause (e) of this subparagraph, all medication packaged and labeled by the issuing pharmacy as a "controlled substance," and syringes and needles, shall be kept in secure, double-locked storage unless all persons in the residence are capable of independent self-administration of medication, and such a procedure does not expose other residents to harm. In family care homes, controlled substances and syringes and needles shall be kept in locked storage.

(e) In all facilities other than supportive community residences, when all persons in the residence are capable of independent self-administration of medication, a controlled substance, syringes, and needles shall be stored in a locked area or container so as to be accessible only to the person for whom it was prescribed, staff who are currently certified to administer medication or who are health care professionals, and family care providers or their substitutes.

(iii) Outdated medication shall not be retained by a facility.

(iv) Discontinued medication shall not be retained by a facility unless specific instructions are received from a prescribing practitioner to do so.

(v) Medication removed from a storage area shall never be left unattended.

(20) Disposal.

(i) Noncontrolled medication. Medication shall be destroyed on the premises in conformance with agency/facility specific policy and procedure which ensures that disposal is carried out only by physicians, physician's assistants, registered nurses, licensed practical nurses, or staff who are certified in medication administration, and (in family care homes) family care providers; the disposal shall be documented.

(ii) Controlled medication. For facilities not holding a Health Department dispensing license, the disposal of controlled substances is to be carried out by two persons. These persons must either be a physician, physician's assistant, registered nurse, licensed practical nurse, a pharmacist, a staff

person certified in medication administration, or (in a family care home) a family care provider with a nurse or the family care case manager. One person is to dispose of the medication and the other is to complete the documentation. For facilities holding a Health Department dispensing license, controlled substances are to be either sent directly to the Bureau of Controlled Substances at the New York State Department of Health, using the current controlled substance surrender form; or destroyed on site after receiving written approval from the bureau in conformance with its current requirements.

(iii) Needles and syringes. All needles and syringes are to be placed in puncture resistant containers immediately after use. When filled, the container should be taken or sent to an approved site for incineration. The disposal shall be documented.

(b) Standards of certification.

(1) If a nonresidential facility does not administer medication, there is documentation that the persons in attendance, parents, guardians or correspondents have been notified of this fact and the expectations should the administration of medication be necessary while a person is at the facility.

(2) There is documentation that at least annually, each person at a residential facility has been evaluated as to his or her ability to self-administer medication. If a nonresidential facility assumes the responsibility for the administration of medication, there is documentation that those persons who do not live in an OMRDD facility have been evaluated by the nonresidential facility, at least annually, as to their ability to administer medication.

(3) Except as specified in paragraph (4) of this subdivision, there is a record for each person in any facility where medication is administered which documents the administration of medication. The record contains:

(i) name of the person;

(ii) name of medication, dosage, and route of administration;

(iii) time and date of administration; and

(iv) signature or initials of the party who supervised, assisted or administered the medication; or of the person who independently self-administered medication. If initials are used, there is a corresponding signature sheet.

(4) In supportive community residences and family care homes:

(i) there is a record as specified in paragraph (3) of this subdivision; or

(ii) for persons who are capable of independent self-administration, there is documentation of the supervision provided by the agency/facility to ensure that the person is taking medication as required.

(5) There is documentation that any person who assisted in the administration of medication, or administered a medication was either:

(i) a physician, dentist, physician's assistant, registered nurse or licensed practical nurse and appropriately licensed at the time of administration; or

(ii) a staff person providing direct care services, as documented by job description, who was certified to administer medication at the time of the administration; or

(iii) a family care provider whose name appears on the operating certificate for the family care home and who received training in conformance with an OMRDD approved curriculum, or a sponsoring agency approved substitute.

(6) There is documentation that all medication being taken by a person residing in an OMRDD operated or certified facility or attending a nonresidential facility where medication is administered has been prescribed, ordered, or approved by a practitioner (except that in a supportive community residence, a family care home, or nonresidential facility, over-the-counter medication may be taken without a physician's prescription, order, or approval if the person taking the medications is capable of independent self-administration of medication).

(7) There is documentation in supportive community residences and family care homes that persons who are capable of independent self-administration of medication have received guidance on the obtaining and use of prescribed and over-the-counter medication.

(8) OMRDD shall verify that the medication regimen of each person in a residential facility has been reviewed at least semi-annually by a registered nurse, physician, physician's assistant, or pharmacist.

(9) OMRDD shall verify that in residential facilities and nonresidential facilities that assume the responsibility for the administration of medication, there is information on each medication being used by each person and that the information is specific to that person, the information is available to staff or the family care provider, and it includes:

(i) name of person taking the medication;

(ii) name of medication;

(iii) directions with regard to correct dose, form, method/route of administration, time of administration;

(iv) start and stop dates, if applicable;

- (v) expected therapeutic effects for the person taking the medication;
- (vi) possible side effects to the person taking the medication; and
- (vii) name of prescribing, ordering, or approving practitioner.

(10) OMRDD shall verify that, except in a supportive community residence or a family care home, all medication is kept in a secure, locked storage area; and controlled substances and syringes and needles are kept in a double locked storage area (unless all persons residing at the facility are capable of independent self-administration of medication, in which case the controlled medication is kept in a locked area or container).

(11) OMRDD shall verify that all medication is stored in its original container.

(12) OMRDD shall verify that all medication containers are labeled and that labels on medication containers are clear and legible.

(13) OMRDD shall verify that there are no outdated medications in designated medication storage areas in the facility.

(14) OMRDD shall verify that there are no discontinued medications in designated storage areas in the facility, unless a prescribing practitioner has specifically instructed that a medication be retained for possible future use; or the agency/facility, under the Department of Health dispensing license, is waiting for authorization from the Department of Health to destroy the medication.

(15) Except in a supportive community residence or family care home, OMRDD shall verify that medication, stored in a refrigerator also used for food, is kept in a separate locked container labeled to indicate that it contains medication.

(16) There is documentation that the training material used to teach medication administration to appropriate staff or family care providers is either:

- (i) the OMRDD curriculum; or
- (ii) a curriculum approved by OMRDD.

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