



State of Connecticut
Department of Developmental Services

DDS

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Notice of Final Agency Action

TO: All Interested Persons

FROM: Peter H. O'Meara, Commissioner

DATE: June 18, 2009

RE: Regulations Concerning Administration of Medications: Residential Facilities, Respite Centers, Day Programs, Community Training Homes, and Individual and Family Supports

The Commissioner of Developmental Services hereby provides Notice of Final Agency Action on regulations concerning **Administration of Medications: Residential Facilities, Respite Centers, Day Programs, Community Training Homes, and Individual and Family Supports.**

Notice of Intent to Amend and Adopt Regulations was published in the Connecticut Law Journal on January 20, 2009. A public hearing to receive testimony concerning the proposed amendments and new regulations was convened on February 2, 2009 at 3:00 p.m. in Room 1A of the Legislative Office Building in Hartford, CT. In addition, written comments were received and considered by the department through February 19, 2009. In response to the testimony and comments received, the following changes are made to the proposed amendments and new regulations:

AMENDMENTS TO PROPOSED REGULATIONS

Sec. 17a-210-1(f)

Definition of "Community training home" has been changed as follows:

[(e)] (f) "Community [T]raining [H]ome" means a private family home licensed by the department to provide residential supports and services [residential facility licensed as such by the department] pursuant to [S]ection 17a-227 [G.S.] of the Connecticut General Statutes.

Sec. 17a-210-1(h) and (w)

The definitions of “Controlled medication” and “Non-controlled medication” have been changed to eliminate the references to Schedule I controlled substances:

(h) “Controlled medication” means controlled substances, Schedules II-V, as defined in section 21a-240 of the Connecticut General Statutes and regulations adopted pursuant to section 21a-243 of the Connecticut General Statutes.

(w) “Non-controlled medication” means those medicinal preparations that are available by prescription or over-the-counter that are not included in Schedules II-V, as defined in section 21a-249 of the Connecticut General Statutes and regulations adopted pursuant to section 21a-243 of the Connecticut General Statutes.

Sec. 17a-210-1(j)

Definition of “Delegation” has been changed as follows:

(j) “Delegation” means the transfer of responsibility for selected nursing tasks from the licensed nurse who is responsible for the overall plan of care for the consumer to qualified non-licensed personnel.

Sec. 17a-210-1(s)

Definition of “Licensed personnel” has been changed to allow pharmacists to be considered “licensed personnel” for purposes of these regulations only when acting in accordance with section 19a-509d of the Connecticut General Statutes:

[(m)] (s) "Licensed [P]ersonnel" means a physician licensed under chapter 370 of the Connecticut [g]General [s]Statutes, a dentist licensed under chapter 379 of the Connecticut [g]General [s]Statutes, a registered nurse licensed under chapter 378 of the Connecticut [g]General [s]Statutes, an advanced practice registered nurse licensed under chapter 378 of the Connecticut General Statutes, a licensed practical nurse licensed under chapter 378 of the Connecticut [g]General [s]Statutes practicing under the direction of a registered nurse or an advanced practice registered nurse, a physician’s assistant licensed under chapter 370 of the Connecticut General Statutes[and]or a pharmacist licensed under chapter 382 of the Connecticut [g]General [s]Statutes[.] and acting in accordance with section 19a-509d of the Connecticut General Statutes.

Sec. 17a-210-1(t)

Definition of “Licensed prescriber” has been changed as follows:

(t) “Licensed prescriber” means a physician or other health care practitioner with applicable statutory authority to prescribe medication.

Sec. 17a-210-1(ll)

Definition of “Trained non-licensed personnel” has been changed removing community training homes from the list of settings where trained non-licensed personnel are required to administer medications:

(ll) “Trained non-licensed personnel” means any person who: (1) is a department-funded, paid employee; (2) is hired by a consumer, the family or guardian of a consumer, or a provider, to provide individual and family support services; (3) has successfully completed training required by the department, pursuant to section 17a-

210-3a of the Regulations of Connecticut State Agencies; and (4) has been approved to administer medication to consumers supported in their own home, family home or specialized day services.

Sec. 17a-210-2(f)

Subsection (f) of section 17a-210-2 (see below) that allowed trained non-licensed personnel to administer medications in community training homes has been removed and the succeeding subsections and internal references have been re-lettered accordingly:

(f) Licensed personnel or trained non-licensed personnel may administer medications to individuals residing in community training homes in accordance with the procedures and requirements established in sections 17a-210-1 to 17a-210-10, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 17a-210-2(g)

Subsection (g) of section 17a-210-2 has been changed to require “written” directions from a licensed prescriber:

(g) Trained non-licensed personnel shall administer all medications according to written directions provided by the licensed prescriber.

Sec. 17a-210-2(k)

Subsection (k) of section 17a-210-2 has been changed to require that the initial administration of suppositories, inhalants or medication instilled in the ears, nose, eyes, gastrostomy tube or jejunostomy tube by certified or trained non-licensed personnel be done under the direct supervision of licensed personnel:

[(i)] (k) [Certified unlicensed personnel shall administer only oral, topical, gastrostomy tube, or jejunostomy tube medications, or inhalant medications, suppositories or medications applied to mucous membranes.] Certified non-licensed personnel and trained non-licensed personnel shall administer only oral, topical or inhalant medications; suppositories; medications given by gastrostomy or jejunostomy tube; or medications applied to mucous membranes. [The prescribing physician may] The licensed prescriber shall require that the initial administration of suppositories, inhalants or medication instilled in the ears, nose, eyes, gastrostomy tube or jejunostomy tube be done under the direct supervision of licensed personnel. Injectable medications may not be administered by certified or trained non-licensed personnel except as necessary for emergency response using premeasured, commercially prepared syringe as provided for in subsection (s) of this section.

Sec. 17a-210-2(q)

Subsection (q) of section 17a-210-2 has been added to set reporting requirements for medication errors in community training homes.

(q) Errors committed by community training home licensees or their designees shall be reported to the consumer, the consumer’s family or guardian, as appropriate, the consumer’s health care provider and the consumer’s nurse or the consumer’s case manager.

Sec. 17a-210-2(s)

Subsection (s) of section 17a-210-2 clarifies emergency medications for use in cases of allergic reactions are not prohibited if prescribed by a licensed prescriber:

(s) Notwithstanding sections 20-14h to 20-14j, inclusive, of the Connecticut General Statutes or any provision in sections 17a-210-1 to 17a-210-10, inclusive, of the Regulations of Connecticut State Agencies, the use of premeasured, commercially prepared syringe or, other emergency medications for emergency response to allergic reactions, with prior approval of the department, shall not be prohibited if prescribed for the consumer by a licensed prescriber.

Sec. 17a-210-3(f)

Subsection (f) of section 17a-210-3 is added to address the administration of medication in community training homes:

(f)(1) Community training home licensees and their designees shall be required to be familiar with general information regarding the safe and correct procedures associated with the administration of medications to consumers residing in their community training home. This information shall be conveyed in a manner identified by the department and shall be reviewed with the licensee by a registered nurse upon initial consumer placement at the community training home and at least annually thereafter.

(2) Information specific to the medications and the administration of the medications to consumers in a community training home shall be provided to the community training home licensee by a licensed prescriber or the consumer's nurse. The community training home licensee shall share this information with each designee who administers medications.

(3) A community training home licensee may be required by a licensed prescriber or a regional director of health services to complete a course of instruction in or demonstrate a proficiency in the administration of medication, including requiring such licensee to attend a department endorsed training program.

Sec. 17a-210-3a

In subsections (a), (b) and (d) of section 17a-210-3a and in the title of the section, references to community training homes have been deleted to reflect that trained non-licensed personnel are not required to administer medications in these settings:

(NEW) 17a-210-3a. Approval process for trained non-licensed personnel for individual and family support: General training in medication administration

(a) Non-licensed personnel paid to provide supports to consumers in individual and family support settings shall be approved to administer medications upon successful completion of the following requirements:

(b) Upon successful completion of general training in medication administration, the name of the non-licensed personnel shall be included in the listing of persons who are identified by the department to have met the requirements for general training in medication administration and are approved to administer medications to consumers supported by individual and family support services.

(d) Non-licensed personnel employed in individual and family support settings that possess current or recent medication certification within the previous 5 years may substitute this experience for the general training in medication administration required by this section unless the following conditions exist:

Sec. 17a-210-4

In the title of section 17a-210-4, community training homes are added as settings where self-administration of medication by consumers may be allowed:

17a-210-4. Self-administration of medications in residential facilities, respite centers, day programs or community training homes

Sec. 17a-210-6(b)

In subsection (b) of section 17a-210-6, the reference to community training homes has been removed to reflect that trained non-licensed personnel will not be required to administer medications in these settings:

(b) In individual and family support settings trained non-licensed personnel shall document the administration of medication to consumers in accordance with the consumer's individual plan.

Sec. 17a-210-10

In subsections (a) and (c) of section 17a-210-10, the references to community training homes has been removed to reflect that trained non-licensed personnel will not be required to administer medications in these settings:

(a) Consumers, consumer's families or guardians, or other persons providing support to a consumer in individual and family support situations may report concerns regarding the administration of medication by trained non-licensed personnel to the consumer's case manager. These concerns shall be reported in writing to the regional director of health services for review.

(c) Trained non-licensed personnel who have been determined as a result of investigative findings to be in violation of the department's general training in medication administration, as defined in section 17a-210-3a of the Regulations of Connecticut State Agencies, shall have their name removed from the list of those trained non-licensed personnel who are approved by the department to provide medication administration to consumers supported by the department in individual and family support situations.

PUBLIC HEARING TESTIMONY AND COMMENT SUMMARY

The department has considered all testimony and comments submitted concerning the proposed amendments and new regulations. Such consideration has resulted in the changes set forth above in the Notice of Final Agency Action and which are reflected in the attached regulations. Some of the comments were not addressed to specific provisions of the proposed amendments and new regulations, while other comments do relate to specific provisions.

- **Comment:** Trained non-licensed personnel administering medications including controlled medications in individual and family support settings without supervision of a licensed nurse.

DDS Response: Trained non-licensed personnel will be administering medication to consumers residing in the consumer's own home or their family's home. This trained non-licensed personnel will only administer medication to the individual consumer they are supporting at that time. This is analogous to the way in which medications are managed or administered for a majority of the population. Trained non-licensed personnel will receive person-specific training regarding their responsibilities to ensure the consumer's health and safety. The expectations for the medication support they will provide to the consumer will be clearly identified.

- **Comment:** Physician oversight would be expected for trained non-licensed personnel.

DDS Response: These revised administration of medication regulations do not identify an expectation that the consumer's health care provider would be responsible to supervise the administration of medication by trained non-licensed personnel. The health care provider in any health care system monitors the medications that he or she prescribes and may identify concerns related to the use of these medications. This does not constitute "supervision" or "oversight" of trained non-licensed personnel. The revised DDS administration of medication regulations do identify that a consumer's health care provider may serve as the source of specific information regarding the medications that the consumer receives.

- **Comment:** Expectation for self-reporting of medication errors by trained non-licensed personnel.

DDS Response: In all situations in which medications are administered either by licensed physicians or nurses, certified non-licensed personnel or trained non-licensed personnel, there is a reliance on an honor system with regards to the reporting of medication errors. The effects of medication errors are not always readily apparent in any person. The general training that is to be provided to trained non-licensed personnel will emphasize the safety measures that prevent errors while also emphasizing the responsibility to promptly report medication errors, and the potential consequences to the consumer if this reporting does not occur. In family homes, the consumer's family would provide oversight to ensure that medications are administered correctly. In a consumer's own home, incorrect medication administration could be identified by the consumer's case manager, the consumer's health care coordinator, if applicable, other workers who support the consumer, or by the person's health care provider through a consumer's clinical presentation or laboratory testing.

- **Comment:** Concerns regarding the administration of medication by any non-licensed personnel.

DDS Response: Certified non-licensed staff has been administering medications in residential and day programs operated, licensed or funded by DDS for more than 15 years. Nursing oversight has been a component of this process because of the types of systems that must be in place to safely manage medication administration to multiple consumers at the same time (e.g., written prescriber orders, medication administration records, controlled drug accountability records, medication re-ordering routines, etc.)

- **Comment:** Impact of the inclusion of staff seeking trained non-licensed personnel status on the DDS administration of medication training system.

DDS Response: The DDS Medication Administration Certification Unit currently provides approximately seven medication certification courses per month that are taught by DDS endorsed instructors at locations in each DDS region. Recently, there have been vacancies in these courses up to two days prior to their start date. On several occasions, certification examinations have been cancelled due to a lack of participants.

Endorsed instructors employed by a private agency also provide option B certification training at a frequency identified by that agency. Accommodations can be made by the Medication Administration Certification Unit for the scheduling of testing sessions to support these private agency courses if these arrangements are made prior to the scheduling of the course.

The potential additional workload for the Medication Administration Certification Unit caused by the addition of classes for trained non-licensed personnel has been identified. Plans to meet these needs both initially and on a long-term basis have been developed.

- **Comment:** Costs associated with staff travel time to attend an administration of medication training.

DDS Response: Training opportunities may be scheduled at a providers administrative offices or other convenient location to reduce the cost of travel. DDS will offer administration of medication training at various locations throughout the state to minimize travel time.

- **Comment:** Costs associated with the need for nursing staff in private agencies to provide administration of medication training.

DDS Response: Private sector, endorsed instructors will have the opportunity to provide the DDS-identified training as desired by a private provider agency. The fiscal impact of the use of private-sector endorsed instructors would need to be considered in light of any increased revenue that might be generated from the ability of the private agency to offer this training in the administration of medications to persons outside the agency seeking to become trained non-licensed personnel.

- **Comment:** Length of the proposed training for trained non-licensed personnel.

DDS Response: The length of time for the course for trained non-licensed personnel has been estimated to be 12 hours based upon the department's experience with successfully providing information to certified non-licensed personnel regarding medication administration including health and safety considerations. As documentation processes will not generally be the responsibility of trained non-licensed personnel as they are for certified non-licensed personnel, the time currently utilized to present this information during the training will not be necessary.

- **Comment:** Community Training Home (CTH) licensed providers and their designees would be required to be trained non-licensed personnel in the administration of medication. Concerns centered on the costs of training for CTH licensees and their designees, nursing oversight requirements, and potential concerns if CTH licensees or their designees could not pass the requirements to become trained non-licensed personnel.

DDS Response: While the department recognizes that CTH providers and their designees would benefit from information provided in the medication administration training, the issues that were raised concerning the training of all DDS CTH licensees and their designees are significant.

The department is removing the requirement that all CTH licensees and their designees be required to achieve trained status. Revised language has been added to the proposed administration of medication regulations that specifies a process for the communication of general information identified to be significant to the issues involving medication administration to DDS consumers (e.g., safety considerations, observation and reporting responsibilities related to medication side effects, etc.) A nurse will periodically review this general information on administration of medication with the CTH licensee. Consumer-specific information will continue to be provided to the CTH licensee by the consumer's health care provider.

- **Comment:** Clarification of the requirement for trained non-licensed personnel to document administration of medication in individual and family support settings in accordance with the consumer's individual plan.

DDS Response: There is no requirement that trained non-licensed personnel document the administration of medication unless this need is specifically identified as part of the consumer's individual plan of support.

- **Comment:** Requirement of an original order from a licensed prescriber at both the day and residential program for the same individual is excessive documentation.

DDS Response: Original orders have been required for both residential and day program sites since the distribution of Health Bulletin #97-1 (Revised July 1999) which states “ Original orders are required per Connecticut statute and regulation for the pharmacist, the individual’s residence, and for the day program. Copies of orders may be used only if they bear the prescriber’s original signature.” Language contained in the proposed revisions to the DDS Administration of Medications Regulations is intended to clarify the definition of original orders and recognize the use of a facsimile transmission as an original order.

- **Comment:** Requirement that prescriptions must be renewed every 180 days represents an increased workload for Day Program staff and would be a financial hardship on families who may be charged for an additional contact with the physician.

DDS Response: Current DDS medication regulations section 17a-210-2(j) indicate that “A prescription for medication shall be limited to a ninety (90) day supply with one refill.” Language in the proposed regulation is intended to clarify that ninety-day plus one refill is 180 days and that a separate prescription is not needed after 90 days unless the facility is ICF/MR certified.

This 180 day requirement was recently specified to include PRN (meaning as needed) medications and over-the-counter (OTC) preparation orders in Nursing Standard #NS09-2 effective June 1, 2009. Situations were identified as part of the department’s quality assurance processes that involved OTC medications ordered for a one year period that were not considered for potential interactions when new medications were prescribed to a consumer or when new health concerns were identified.

- **Comment:** Several changes were suggested to clarify or improve definitions in these regulations (i.e., delegation (17a-210-1(j)), licensed prescriber (17a-210-1(t)), original orders (17a-210-1(x))

DDS Response: Suggestions for the improvement and clarification of definitions were accepted and the changes were made.

- **Comment:** For the purposes of these regulations including pharmacists in the definition of licensed personnel.

DDS Response: Pharmacists, for the purposes of these regulations, will be considered licensed personnel when acting in accordance with section 19a-509d of the Connecticut General Statutes. Subsection (s) of section 17a-210-1 has been reworded to reflect this narrowed definition.

- **Comment:** Trained non-licensed personnel should have written orders from a licensed prescriber, and
- **Comment:** Initial administration of medications by trained non-licensed personnel should be required to be witnessed by a nurse.

DDS Response: DDS does not intend to require persons living in family homes or their own homes to have written orders from licensed prescribers in place of directions indicated on a pharmacy label as prescribed by their health care provider. Consumer specific training required for trained non-licensed personnel would include the proper administration of medications by the prescribed routes.

- **Comment:** Inaccurate information regarding the administration of controlled substances with the inclusion of Schedule I drugs in the list of controlled medications.

DDS Response: In subsections (h) and (w) of 17a-210-1, Schedule I drugs were inadvertently included in the definitions of “controlled medication” and “non-controlled medication.” Schedule I drugs have been removed from both definitions.

- **Comment:** Question regarding the requirement for certified non-licensed personnel to have a worksite practicum at each home where they administer medications.

DDS Response: The requirement for worksite-specific and person-specific training mirrors the requirement for nurses to provide consumer-specific training prior to delegating responsibility to certified non-licensed personnel. The concerns identified by providers have been clarified in DDS Nursing Standard #NS 09-4 that specifies acceptable options for meeting the need for consumer-specific and worksite-specific information prior to delegation.