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Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Department of Intellectual and Developmental Disabilities
Division:	
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	Brenda Clark
Address:	Harrington House, CBDC, 275 Stewarts Ferry Pike, Nashville, TN 37214
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Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	CBDC, One Cannon Way		
Address 2:	275 Stewarts Ferry Pike		
City:	Nashville		
Zip:	37214		
Hearing Date :	01/12/2015		
Hearing Time:	1 PM- 3:30 PM	<input checked="" type="checkbox"/> CST/CDT	
		<input type="checkbox"/> EST/EDT	

Additional Hearing Information:

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Revision Type (check all that apply):

- Amendment
- New
- Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0465-01-03	Administration of Medication by Unlicensed Personnel

Rule Number	Rule Title
0465-01-03-.01	Purpose
0465-01-03-.02	Definitions
0465-01-03-.03	Medication Administration Training Program

Chapter Number	Chapter Title
0465-01-03	Administration of Medication by Unlicensed Personnel
Rule Number	Rule Title
0465-01-03-.04	Approval of Unlicensed Personnel
0465-01-03-.05	Certification of Unlicensed Personnel
0465-01-03-.06	Limitations of Functions of Unlicensed Personnel

Chapter Number	Chapter Title
0465-01-03	Administration of Medication by Unlicensed Personnel
Rule Number	Rule Title
0465-01-03-.07	Provider Agency Requirements
0465-01-03-.08	Termination of Authority to Administer Medication
0465-01-03-.09	Monitoring of Unlicensed Personnel

Chapter Number	Chapter Title
1200-20-12	Administration of Medication by Unlicensed Personnel Administration of Medication by Unlicensed Personnel
Rule Number	Rule Title
1200-20-12-.01	Repealed
through	
1200-20-12-.08	Repealed

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

New Rules

0465-01-03

Administration of Medication by Unlicensed Personnel

0465-01-03-.01 Purpose:

The purpose of these rules is to amend the former rules pertaining to Administration of Medication by Unlicensed Personnel and establish new rules in light of the Department of Intellectual and Developmental Disabilities' current organization, structure and resources.

0465-01-03-.02 Definitions: As used in these rules, the terms below shall have the following meanings ascribed to them.

- (1) "Administration of Medications" shall mean providing for the ingestion, application, injection of medications allowed by these rules, inhalation or rectal or vaginal insertion of medication, including over the counter and prescription drugs, according to the written or printed directions of the prescribing practitioner and making a written record thereof with regard to each medication administered, including the time and amount taken. Administration does not include judgment, evaluation or assessment.
- (2) "Certification" shall mean the period of time an unlicensed staff is authorized to administer medications in accordance with these rules.
- (3) "Certified Personnel" authorized to administer medications shall mean an employee who:
 - (a) Is at least 18 years of age;
 - (b) Has met all requirements to be an employee of a provider agency;
 - (c) Is able to effectively read, write and communicate verbally in English and read and understand instructions, perform record-keeping duties and write reports;
 - (d) Has successfully completed the DIDD medication administration training program; and
 - (e) Holds current certification to administer medications according to the provision of these rules.
- (4) "Competency Testing" shall mean a written examination and a practical demonstration of skills that measure basic proficiency in medication administration.
- (5) "Curriculum" shall mean the current course training program 'Medication Administration for Unlicensed Personnel'.
- (6) "Department" shall mean the Tennessee Department of Intellectual and Developmental Disabilities, also referred to as DIDD.
- (7) "Drugs or Medications" shall mean substances intended for use in diagnosis, care, mitigations, treatment or prevention.
- (8) "Employee" shall mean an individual who is unlicensed and is employed or receives payment through a provider agency contracting with the Department.
- (9) "Medication Variance" shall occur at any time a medication is given in a way that is inconsistent with how it was ordered by the prescribing practitioner and in accordance with the "Eight Rights" (i.e. right dose, right drug, right route, right time, right position, right texture, right person and right documentation).

- (10) "Injectable Medications" shall mean medications given by intradermal, subcutaneous, intramuscular or intravenous routes. Injectable medications that may be given by certified unlicensed personnel are limited to routine insulin injections (with additional training) or injectable epinephrine (EpiPen). Routine insulin injections shall mean insulin that is pre-drawn/prepared by the pharmacy and is ordered on a regular basis. Administration of sliding scale insulin, mixing of insulin's, or any administration requiring assessment and judgment is not allowed under the exemption.
- (11) "Monitoring" shall mean periodic review, observation, direction, and evaluation of a certified unlicensed staff's knowledge, skills and performance related to the functions and activities provided for in these rules.
- (12) "Participant Record" shall mean the official record from the Department containing all information relative to class participation. Participant record is the only acceptable documentation for proof of certification to administer medications under the exemption.
- (13) "RN Trainer" shall mean a registered nurse holding an unencumbered license in the State of Tennessee and who is trained by the Department to provide medication administration training in accordance with the curriculum and these rules.
- (14) "Person (receiving services)" shall mean any person with intellectual and or developmental disabilities who is enrolled in a DIDD home and community based waiver program and any person served by an agency that is both licensed under Title 33 and under contract with DIDD to provide residential or day services for people with intellectual disabilities, including persons served in the CHOICES program.
- (15) "Provider Agency" shall mean private non-profit or for-profit entity under agreement/contract with the Department to provide services to individuals with intellectual and/or developmental disabilities.
- (16) "Termination" shall mean the permanent revocation of certification and authority for;
 - (a) Unlicensed staff to administer medication; or
 - (b) RN trainer to train the curriculum.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.03 Medication Administration Training Program

- (1) Medication Administration Curriculum developed and administered by the Department.

The course curriculum should cover, at a minimum, the following:

- (a) Legal and ethical aspects of medication administration;
- (b) State and federal regulations regarding medications;
- (c) Terminology, abbreviations and measurements;
- (d) Administration of medications;
- (e) Types of medications, indications, actions, side effects and appropriate emergency response;
- (f) Documentation and;

- (g) Storage of medications.
- (2) Certified RN Trainers
 - (a) The instruction of medication administration must be performed by a registered nurse licensed and registered in the State of Tennessee and has:
 - (1) A minimum of two (2) years RN experience;
 - (2) A minimum one (1) year experience in the provision of services to people within the DIDD system; and
 - (3) Experience as a direct supervisor responsible for oversight and management of staff.
 - (b) RN Trainer must maintain security of all testing materials.
 - (c) Training for RN trainer will be provided in accordance with Departmental rules and standards.
 - (d) The Department will maintain a current database of certified RN trainers who are eligible to provide the instruction of medication administration under the exemption.
 - (e) The Department may terminate an RN trainer's certification for non-compliance with the Department's rules and standards. The RN trainer may also be terminated without cause for any reason determined by the Department.
 - (3) The Department is expected to keep abreast of current standards and practices in the field and update the program accordingly.
 - (4) Competency Based Medication Administration Program:
 - (a) The Department shall assure that training sessions are held in accordance with these rules;
 - (b) Provider agencies must develop and maintain a system for ensuring that any staff administering medications has current certification in Medication Administration for Unlicensed Personnel;
 - (c) The Department will maintain course material for one (1) year and participant records indefinitely;
 - (d) The Department will provide the agency with a participant record for each participant registered for class.

Authority: T.C.A. 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.04 Approval of Unlicensed Personnel

- (1) Any contracted DIDD provider agency employing staff who are not otherwise authorized by law to

administer medications shall be allowed to perform such duties only after passing competency testing. An employee who administers medications within the provision of this paragraph shall be exempt from the licensing requirements of the Nurse Practice Act and the Rules of the Board of Nursing.

- (2) Before administering medications, an unlicensed employee must successfully complete the medication administration program consisting of not less than twenty (20) hours of classroom instruction as set forth in these rules.
- (3) To successfully complete a medication administration training program, an unlicensed employee shall achieve a score of at least 80 for the course based on a written, objective test on the components set forth in these regulations. Demonstrated proficiency in the practicum of medication administration is also required with a score of at least 80.
- (4) Certification must be renewed every three (3) years by:
 - (a) Successfully completing the program; or
 - (b) Test-out; by completion of online review followed by successfully passing the written and practical tests administered by the Department.
- (5) An employee who does not achieve a score of at least 80 on the written or practical test is eligible for a total of three (3) consecutive attempts. At any point successful completion is achieved, three (3) consecutive attempts resume. Eligibility for the third attempt shall be at least six (6) months from the second. If such individual fails to meet minimum competency requirements during the third test, the employee cannot take the course again, nor shall the employee be allowed to administer medications.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.05 Certification of Unlicensed Personnel

- (1) The provider agency shall obtain proof of certification (participant record) for new employees from the Department before they are allowed to administer medications.
- (2) The Department shall verify an employee's current status and date of last successful completion of medication administration training program.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-4-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.06 Limitations of Functions of Unlicensed Personnel

- (1) The following may be performed by unlicensed personnel under the scope of these regulations and in accordance with the training curriculum:
 - (a) Medication administration via the following routes: oral, rectal, vaginal, eye, ear, nasal and topical.
 - (b) Administration of medications by subcutaneous route for routine insulin (with additional training) and injectable epinephrine (EpiPen).
- (2) This regulation does not preclude the performance of procedures by unlicensed personnel pursuant to individual delegation by licensed personnel in accordance with the Nurse Practice Act

and the Rules of the Board of Nursing.

- (3) Administration of medications included in this exemption cannot be delegated.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.07 Provider Agency Requirements

- (1) A provider agency employing unlicensed personnel must have a written policy demonstrating compliance with these rules for any employee who administers medications. This policy must be accepted by the Department and must include, at a minimum, the following elements:
 - (a) Medication Prohibitions;
 - (b) Security;
 - (c) Program Requirements;
 - (d) Medication Storage and Labeling;
 - (e) Editing of Medication Records;
 - (f) Medication Refusal;
 - (g) Medication Administration Record (MAR);
 - (h) Controlled Substances;
 - (i) Medication Variances;
 - (j) Medication Disposal;
 - (k) Family Visit; and
 - (l) Self-Administration.
- (2) A provider agency must have a separate Medication Administration Record (MAR) of ordered medications for each person. The MAR must include at least the following:
 - (a) Name of person receiving the medication;
 - (b) Name of medication, indication, dosage and route of administration;
 - (c) Time and date of administration;
 - (d) Name of prescribing practitioner;
 - (e) Start date and stop dates, if applicable; and
 - (f) Any specific directions.
- (3) A provider agency must maintain a side effects sheet and practitioner orders with the MAR for each medication ordered. Such records will be subject to review by the Department.
- (4) Storage, security and disposal of medications are maintained in accordance with State and Federal laws and DIDD regulations.
- (5) The agency must have certified staff available to administer medications as ordered and at a place convenient for the person.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.08 Termination of Authority to Administer Medication

- (1) The provider agency may submit a recommendation to the Department for termination of authority to administer medications in the event a certified employee is determined to be unable to safely administer medications due to:
 - (a) The use of drugs, alcohol or controlled substances which could impair judgment; or
 - (b) Performance of unsafe or unacceptable care of people receiving medications; or
 - (c) Failure to conform to the essential and prevailing standards of medication administration.

The Department shall review the recommendation and provide a decision to the provider agency. Termination of certification notice will be provided to the employee by certified mail.

- (2) The certified employee may have the authority to administer medication terminated without cause for any reason determined by the Department.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

0465-01-03-.09 Monitoring of Unlicensed Personnel

- (1) The Department will monitor the administration of medications by unlicensed personnel. Monitoring will be completed by registered nurses employed by the Department.
- (2) The agency will monitor, at a minimum, the first medication pass of the unlicensed personnel upon successful completion of their original certification, provide ongoing monitoring in accordance with agency policy and maintain documentation of such.

Authority: T.C.A. §§ 4-5-202, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 68-1-904. Administrative History: Original rule filed August 21, 1998; effective November 4, 1998.

Repeals

Chapter 1200-20-12 is repealed in its entirety.

Authority: This statement is made in accordance with T.C.A. §4-5-201 *et seq.* Tenn. Code Ann. (T.C.A.) §§ 33-1-302 & 303; 33-1-309 (d); 33-1-304.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: 11/20/14

Signature: DPayne

Name of Officer: Debra K. Payne

Title of Officer: Commissioner



Subscribed and sworn to before me on: 11/20/14

Notary Public Signature: Lisa Michelle Stephenson

My commission expires on: 5/3/16

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Filed with the Department of State on: 11/20/14

Tre Hargett

Tre Hargett
Secretary of State

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