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 Rule ID(s): 10010, 1011
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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Department of Intellectual and Developmental Disabilities
Division:	
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

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

Chapter Number	Chapter Title
1200-20-12	Administration of Medication by Unlicensed Personnel to People with Mental Retardation
Rule Number	Rule Title
1200-20-12-.01	Repealed
through	
1200-20-12-.08	Repealed

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

Chapter Number	Chapter Title
0465-01-03	Administration of Medication by Unlicensed Personnel
Rule Number	Rule Title
0465-01-03-.05	Certification of Unlicensed Personnel
0465-01-03-.06	Limitations of Functions of Unlicensed Personnel
0465-01-03-.07	Provider Agency Requirements
0465-01-03-.08	Termination of Authority to Administer Medication

Chapter Number	Chapter Title
0465-01-03	Administration of Medication by Unlicensed Personnel
Rule Number	Rule Title
0465-01-03-.09	Monitoring of Unlicensed Personnel

Repeal

Chapter 1200-20-12
Administration of Medication by Unlicensed Personnel
To People with Mental Retardation

Chapter 1200-20-12 Administration of Medication by Unlicensed Personnel to People with Mental Retardation is repealed in its entirety.

Authority: T.C.A. §§ 4-5-201 *et seq.*; 33-1-302; 33-1-303; 33-1-304; and 33-1-309(d)

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 as well as 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 mean 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 that are pre-drawn/prepared by the pharmacy and ordered on a regular basis (with additional training) or injectable epinephrine (i.e. EpiPen).
- (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 and/or developmental 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 Programs

- (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 shall be performed by a Registered Nurse licensed and registered in the State of Tennessee who has:
 - (1) A minimum of two (2) years RN experience;
 - (2) A minimum one of (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 shall maintain security of all testing materials.
 - (c) Training for RN trainer shall be provided in accordance with Departmental rules and standards.
 - (d) The Department shall maintain a current database of certified RN trainers who are eligible to provide the instruction of medication administration under the exemption.
 - (e) The RN Trainer's authority to provide training in Medication Administration for Unlicensed Personnel may be terminated by the Department for failure to conform and perform to the standards set forth in these rules and the curriculum. Notice shall be provided to the RN Trainer by certified mail and he/she shall have the right to request an appeal hearing of decision to terminate his/her authority to provide training, pursuant to the Tennessee Uniform Administrative Procedures Act.
- (3) The Department shall 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 ensure that training sessions are held in accordance with these rules;
 - (b) Provider agencies shall develop and maintain a system for ensuring that any certified personnel administering medications have current certification in Medication Administration for Unlicensed Personnel;
 - (c) The Department shall maintain course material for one (1) year and participant records for five (5) years; and
 - (d) The Department shall provide the agency with a participant record for each participant registered for class.

Authority: T.C.A. 4-5-202, 4-5-301, 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. Certified personnel who administer 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 employee shall successfully complete a 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 employee shall achieve a score of at least 80 percent (%) 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 shall also be required with a score of at least 80 percent (%).
- (4) Certification shall be renewed every three (3) years by:
 - (a) Successfully completing the Medication Administration for Unlicensed Personnel program or
 - (b) Test-out; by completion of online review followed by successfully passing the written and practical tests administered by a certified RN Trainer.
- (5) DIDD shall allow employees who failed under the previous system to start fresh under the new system. DIDD shall remove any limit on the number of times an employee may take the exam with no waiting period between attempts. After the second failure of the employee to pass the examination, the cost of further testing shall be shifted to the provider.

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 the 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 certified 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; and
 - (b) Administration of medications by subcutaneous route for routine insulin (with additional training) and injectable epinephrine (i.e. EpiPen).

- (2) This regulation does not preclude the performance of procedures by certified 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 certified personnel shall have a written policy demonstrating compliance with these rules. This policy shall be accepted by the Department and shall 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 shall 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 date, if applicable; and
 - (f) Any specific directions.
- (3) A provider agency shall maintain a side effects sheet and practitioner orders with the MAR for each medication ordered. Such records shall be subject to review by the Department.

- (4) Storage, security and disposal of medications shall be maintained in accordance with State and Federal laws and DIDD regulations.
- (5) The agency shall have certified personnel available to administer medications as ordered and at a place and time 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 shall submit a recommendation to the Department for termination of authority to administer medications in the event a certified personnel 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 shall be provided to the certified personnel by certified mail and he/she shall have the right to request an appeal hearing on his/her termination of authority to administer medications, pursuant to the Tennessee Uniform Administrative Procedures Act.

Authority: T.C.A. §§ 4-5-202, 4-5-301, 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 shall monitor the administration of medications by certified personnel. Monitoring shall be completed by Registered Nurses employed by the Department.
- (2) The provider agency shall monitor, at a minimum, the first medication pass of the certified personnel upon successful completion of his/her 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.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the DIDD (board/commission/ other authority) on 8/4/15, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 11-20-14

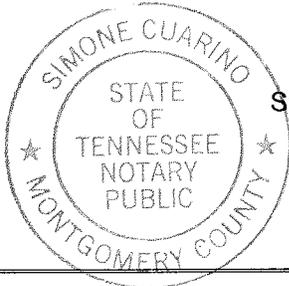
Rulemaking Hearing(s) Conducted on: (add more dates). 1-12-15

Date: 8-4-15

Signature: Debra K Payne

Name of Officer: Debra K Payne

Title of Officer: Commissioner



Subscribed and sworn to before me on: 8/4/15

Notary Public Signature: [Signature]

My commission expires on: 7/11/2017

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slattery III
Herbert H. Slattery III
Attorney General and Reporter
8/20/2015
Date

Department of State Use Only

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Filed with the Department of State on: 08/28/15

Effective on: 11/26/15

[Signature]
Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

See Attached.

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
1.	<p>I agree with what every one of these ladies has said. The six month waiting period is not only difficult for the staff person because they lose that information over the six-month period, but if they can't give medications, they will also likely lose their job. And with staff shortages across the state, and the grade system the way it is, and us having to pay staff what we can pay them, we really don't need to lose good staff because of that particular regulation.</p> <p>Reiterating what they had to say about only the three attempts to pass the course. I'm a registered nurse. The board of nursing, after failing two times, any subsequent retesting is on a case-by-case basis, and there is no set limit. I understand that there's a cost involved every time someone has to take the test again. Perhaps, the recommendation would be after the second attempt, that the cost goes to the provider. The provider might have very good reasons where you've got a good caregiver but, for whatever reason, they're not the best test takers. I have peers that it took them more than a couple of times to pass the boards. Great nurses, great on-the-spot critical thinking, just not very good test takers, and they get a little nervous.</p> <p>I think when the required fiscal impact study is done, you'll find that that is a – that will</p>	<p>Betty McNeely, Journeys in Community Living, and I also represent the TNCO regulatory committee</p> <p>Tonya Copeland with Evergreen Life Services and TNCO</p> <p>Melanie Keller, Meritan & TNCO</p> <p>Cindy Graves, Impact Centers & TNCO</p> <p>Comments submitted in writing:</p> <p>Jeanene Houston, Hilltoppers</p> <p>Jennifer Enderson, Emory Valley Center</p> <p>Piete Ferguson, RN-BC</p> <p>Robin Atwood, TNCO</p>		<p>Concur. DIDD will allow staff who has failed under the previous system to start fresh under the new system. DIDD will also remove the limit on the number of times an individual can take the exam. DIDD also concurs that after the second fail the cost should be shifted to the provider. This will be addressed in the next revision of the provider manual.</p> <p>Concur. Will revise to remove the six month wait period.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
	<p>have an impact on costs for providing services, the costs the providers face. And another thing that will show up in the fiscal impact study is the cost of having to either take a four-day course for recertification or travel to the regional office to have the nurses test them out.</p>	<p>Community Services Aurelia Kanarski, Life Bridges. Damaris Betancourt, Life Bridges. Bonnie Guthrie, Lakeway Achievement Center Patricia Calfee, Life Bridges</p>		
2.	<p>The online training is an excellent opportunity for recertification, and I think it's great. We trust online training for all other subjects, except First Aid. And I do not understand why we can take the online training but can't take that online test.</p> <p>In regards to the recertification, I think that's fantastic that there is the opportunity to review online. However, I'm curious as to why the testing would have to be done by the regional nurse, as opposed to the trainer that's already been approved to teach the curriculum. There are several caregivers, several homes, agencies, that are two to three hours away from a regional office. So that is a burden on the direct support staff to</p>	<p>Cindy Graves, Impact Centers & TNCO Melanie Keller, Meritan & TNCO Comments submitted in writing. Jeanene Houston, Hilltoppers Jennifer Enderson, Emory Valley Center</p>	TCA Title 33	<p>Do not concur. Security of the testing process cannot be assured by permitting online testing. Thank you for the question. Concur. DIDD will remove this requirement of testing by the regional nurse from the rules.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
	have to travel as well as the agencies to cover that.	Phillip Garner, Buffalo River Services Robin Atwood, TNCO Damaris Betancourt, Life Bridges Patricia Calfee, Life Bridges		
3.	The Medication Administration Certification can be terminated without cause, that's in regards to the nurses that have been approved to teach. And I certainly understand any rule violations or not following policy and procedures, I just don't understand the need that they can just be terminated without cause for no reason.	Melanie Keller, Meritan & TNCO Comments submitted in writing. Jeanene Houston, Hilltoppers Nancy Thiessen, Comcare William Hubbard, Attorney Robin Atwood, TNCO		Concur. This language will be amended to allow for notice and a contested hearing.

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
		<p>Aurelia Kanarski, Life Bridges</p> <p>Bonnie Guthrie, Lakeway Achievement Center</p>		
4.	<p>Going back to the requirements for certified trainers, the requirement for the nurse to have a year's experience supporting people in the DID system and the one-year supervisory experience, I don't see how that has any direct correlation with somebody's ability to teach the class and assess someone's knowledge and appropriately grade a test. Supervisory experience and DIDD experience is not necessarily pertinent to teaching curriculum.</p>	<p>Melanie Keller, Meritan & TNCO</p> <p>Comments submitted in writing.</p> <p>Jeanene Houston, Hilltoppers</p> <p>Jennifer Enderson, Emory Valley Center</p> <p>Nancy Thiessen, Comcare</p> <p>Robin Atwood, TNCO</p> <p>Aurelia Kanarski, Life Bridges.</p> <p>Damaris Betancourt, Life Bridges.</p>		<p>Do not concur.</p> <p>There has always been a 2 year RN experience requirement with a minimum of 1 year experience in the provision of services to people within the DIDD system. Health care supports for people supported by DIDD can be quite different from supports for people without disabilities. For training to be valid and real for the participant, the trainer must have experience and examples to use in the teaching. Without experience, the training may be more theoretical and not prepare the learners for the challenges they may face. It is a quality of training issue.</p> <p>A trainer must be able to control the class so each learner receives appropriate attention; therefore some supervisory experience is appropriate.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
5.	<p>In regards to the CHOICES piece, it's not very clear to me if this is saying that all of the DIDD Medication Administration Rules will be applied to anyone that provides community living support through CHOICES, even if that's all that's in the home are CHOICES recipients, as opposed to a blended home with CHOICES and DIDD.</p>	<p>Melanie Keller, Meritan & TNCO</p> <p>Comments submitted in writing.</p> <p>Jeanene Houston, Hilltoppers</p> <p>Robin Atwood, TNCO</p>		<p>Medication administration is permissible by staff who are currently certified in medication administration and employed by an HCBS waiver provider who is both licensed under Title 33 AND contracted with DIDD to provide services through an HCBS waiver operated by DIDD. Staff certified in medication administration and employed by a DIDD licensed and contracted HCBS provider may administer medications to DIDD waiver participants and to CHOICES CLS participants as appropriate. This includes blended homes and homes that are comprised of CHOICES CLS residents only, so long as the provider is licensed by DIDD pursuant to Title 33, and in addition to being contracted with an MCO is contracted with DIDD for the provision of HCBS waiver services under one of the state's 1915(c) waivers and administering staff are certified in medication administration. Providers who are not both licensed by DIDD pursuant to Title 33 AND contracted with DIDD for the provision of HCBS waiver services under one of the state's 1915(c) waivers are not permitted to have unlicensed staff administer medications. All requirements of the Nurse Practice Act will apply.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
6.	<p>Just a request, that when the rules are updated, when it's final, that the provider agencies be allowed to update their Medication Administration Policies to reflect the changes without having to go through the process of the Medication Administration Policy being reviewed and approved. If all that we're adding are the changes that are in the rules, it seems like that would be a long process to go through.</p>	<p>Melanie Keller, Meritan & TNCO</p> <p>Comments submitted in writing.</p> <p>Jeanene Houston, Hilltoppers</p> <p>Jennifer Enderson, Emory Valley Center</p> <p>Nancy Thiessen, Comcare</p> <p>Robin Atwood.</p> <p>Aurelia Kanarski, Life Bridges</p>	<p>Provider Manual 8.5.a</p>	<p>Do not concur. Provider manual 8.5.a Medication Administration by Unlicensed Personnel. 1. Providers shall have a medication safety policy (formerly known as medication administration policy) that is accepted by DIDD. If the only changes in the medication safety policy are the changes to the rules, DIDD review and approval will be straightforward and completed expeditiously.</p>
7.	<p>We strongly recommend that the Department develop a medication administration workgroup. We hope that there will be an ongoing committee appointed that will include providers, the nurse trainers, training specialists from the agencies to review curriculum on an ongoing basis, to review the rules on an ongoing basis, and to make sure the decisions are made that are based on what is actually going on in the field so that we have what Dr. Cheetham referred to as</p>	<p>Betty McNeely, Journeys & TNCO</p> <p>Comments submitted in writing</p> <p>Jeanene Houston, Hilltoppers</p> <p>Robin Atwood, TNCO</p>		<p>Duly noted. DIDD will take under advisement.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
	"ongoing quality improvement" in the program.			
8.	Under medication variances, there is a comment about the right documentation being added to the rights under what would be reported as a medication variance. A documentation error is a documentation error, but somebody simply initialing under the wrong boxes, that's quickly noted and corrected, and should not be included as a medication variance.	<p>Melanie Keller, Meritan</p> <p>Comments submitted in writing.</p> <p>Jeanene Houston, Hilltoppers, Inc.</p> <p>Nancy Thiessen, Comcare.</p> <p>Robin Atwood, TNCO</p> <p>Aurelia Kanarski, Life Bridges.</p>		Do not concur. This requirement came from materials from the Regulatory Relief work group and was accepted. The purpose of medication variance data is to continuously improve the safe administration of medications.
9.	Another comment in regards to the training and the 20-hour timeframe. I am licensed to teach med-admin through DIDD and have also taught through DCS. DCS has a 4-hour training, as opposed to a 20-hour training. For me trying to process the difference between administering the medication to a 16-year old child, or when they turn 18, now you have to have 20 hours to do what you've been doing all along, I just have a difficult	<p>Melanie Keller, Meritan</p> <p>Tonya Copeland, Evergreen Life Services & TNCO</p> <p>Comments submitted in writing.</p>		Do not concur. There are different requirements in a home health setting where the person or family member is trained on some procedure and what is permitted under the exemption for medication administration. The standards to which the person who is trained are different. The curriculum revisions had to be approved by the board of nursing and the not less than

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
	<p>time processing that. I have gone in and taught an 80 year old person, without even a high school education, how to catheterize, how to administer IV antibiotics, how to check blood sugars and administer insulin, and you do that in one to two visits of a couple of hours apiece. So even the 20 hours, to me, seems excessive for what we're able to do on a day-to-day basis.</p> <p>Reminder: a fiscal impact study must be completed on this and other changes to the rules/curriculum.</p>	<p>Jeanene Houston, Hilltoppers Robin Atwood, TNCO</p>		<p>20 hours was part of the existing curriculum.</p> <p>In regards to the fiscal impact, that is duly noted and DIDD will file the statement with the final version of the rules.</p>
10.	<p>I would like to add to the fact that supervisory experience to be a trainer—I do not feel that is a necessity, and should not be a requirement for the trainers just because that's not something that they have to have in order to be able to teach a class and administer tests.</p>	<p>Aurelia Kanarski, Life Bridges Comments submitted in writing. Jennifer Enderson, Emory Valley Center Jeanene Houston, Hilltoppers.</p>		<p>Do not concur. A trainer must be able to control the class so each learner receives appropriate attention; therefore some supervisory experience is appropriate.</p>
11.	<p>I would like to suggest oxygen administration be added to the curriculum for medication administration, and no longer require a delegation for unlicensed staff to administer. The administration of oxygen is much less of a potential danger to our consumers than</p>	<p>Steve Leach, Frontier Health Comments submitted in writing</p>		<p>Department of Health rules explicitly prohibit oxygen administration from being part of medication administration by unlicensed personnel currently. Department of Health rules explicitly permit under State law (see 1200-20-12-.05(1)(g)). To be clear, this is a task</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
	<p>some of the oral medications unlicensed staff provides, and I cannot understand why a delegation is required for oxygen to be administered. I understand oxygen given in too large a dose to someone who has emphysema could have serious consequences, but then giving too much of any med could be dangerous and potentially lethal to the recipient. I do not see a level of clinical expertise in oxygen administration that would require a delegation, and would recommend it be included in the curriculum for medication administration for unlicensed personnel.</p>			<p>that a nurse can individually delegate to an unlicensed person; however it cannot be performed as part of the medication administration certification, absent a change in DOH rules. Additional research would also be required to determine whether changes would also be required in the law.</p>
12.	<p>1) The Regulatory Relief Task force, which I was part of, first raised this issue 3 years ago. It is disappointing that it took so long for changes to be made, and that several deadlines were missed. 2) The original goal behind the proposal for the curriculum change was to simplify it and reduce the cost, in part by making it 2 days/16 hours. Again it is disappointing this has not happened.</p>	<p>Comments submitted in writing. Mike McElhinney, Michael Dunn Center</p>		<p>In regards to points 1 and 2, your concerns are noted.</p>
13.	<p>Here are the parts I see issues with: Definitions: (1) "Administration does not include judgment, evaluation or assessment". Is that not the staff are doing when they have to enter a result for a PRN medication? (Especially for non-verbal clients).</p>	<p>Comments submitted in writing. Aurelia Kanarski, Life Bridges</p>		<p>Do not concur. To administer a PRN, a doctor's order is required identifying specific parameters by which the medication is to be administered. This does not require judgment, evaluation or assessment.</p>

#	Comment	Source	Policy/Rule/TCA Reference	DIDD Response
14.	0465-01-03-.09- Leave the monitoring statement as it was previously.	<p>Comments submitted in writing. Aurelia Kanarski, Life Bridges</p> <p>Damaris Betancourt, Life Bridges</p>		Do not concur. To ensure the person can safely administer medications, one observation of performance on the job is a minimal standard.
15.	Require DIDD to have training classes for RN's to teach classes more often or as needed.	<p>Comments submitted in writing. Bonnie Guthrie, Lakeway Achievement Center</p>		The Department must continue to operate within the budgetary appropriations that are afforded us, and at this time we would be unable to consider this request.
16.	Allowing the certification to run the whole time rather than require the staff be recertified after leaving an agency and then returning, or a refresher test not the whole 4 day class. Unreasonable.	<p>Comments submitted in writing. Bonnie Guthrie, Lakeway Achievement Center</p>		A person who holds a current certification and changes employer (i.e. one DIDD provider agency) would require only proof of valid certification from the former employer. The certification is for three (3) years regardless of where the person is employed.

**RULES
OF
TENNESSEE DEPARTMENT OF ~~HEALTH~~
INTELLECTUAL AND DEVELOPMENTAL
DISABILITIES**

**CHAPTER ~~1200-20-12~~
0465-01-03
ADMINISTRATION OF MEDICATION BY UNLICENSED PERSONNEL
TO PEOPLE WITH MENTAL RETARDATION**

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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 ~~1200-20-12-.01~~ DEFINITIONS: As used in these rules, the terms below shall have the following meanings ascribed to them.

- (1) "Administration of ~~medications~~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 ~~attending physician prescribing practitioner; or other authorized practitioner~~ or as written on the prescription label and making a written record thereof with regard to each medication administered, including the time and amount taken, ~~but a~~ Administration does not include judgment, evaluation or assessment.
- (2) ~~"Adult day programs" shall mean any program licensed or contracted by the Division of Mental Retardation Services to provide day activities to people with mental retardation over eighteen years of age. Such services include day habilitation, follow along, supported employment and community participation.~~
- (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:

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- (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, ~~wright~~ write and communicate verbally in English ~~and as well as 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 provisions of these rules.
- (4)(3) "Competency testing" shall mean a written ~~exam~~ examination and a practical demonstration of skills that measure basic ~~competency~~ proficiency in medication administration.
- (4) ~~"The Board" shall mean the Tennessee Board of Nursing~~
- (5) "Curriculum" shall mean ~~a detailed course outline, description or syllabus submitted to the Department as part of the approval process of an entity, nursing agency, health care facility or Division sponsoring a medication administration course. At a minimum, a curriculum for approval or re-approval shall contain the following:~~ the current course training program 'Medication Administration for Unlicensed Personnel'.
- (a) ~~title~~
 - (b) ~~names and authors~~
 - (c) ~~specific course objectives~~
 - (d) ~~units to be covered in the course~~
 - (e) ~~hours to be spent in each unit~~
 - (f) ~~the methods of instruction~~
 - (g) ~~a description of the practical training to be provided~~
 - (h) ~~a written test to measure competency in medication administration; and~~
 - (i) ~~a description of a test to measure competency through a practical demonstration of each required skill~~
- (6) "Department" shall mean the Tennessee Department of ~~Health~~ Intellectual and Developmental Disabilities, also referred to as DIDD.
- (7) ~~"Division" shall mean the Division of Mental Retardation Services of the Department of Mental Health and Mental Retardation.~~
- (7)(8) "Drugs or Medications" shall mean substances intended for use in diagnosis, care, mitigations, treatment, or prevention.
- (8)(9) "Employee" shall mean an individual who is unlicensed and is employed ~~by~~ or receives payment through a provider agency contracting with the Department.
- (9)(10) "Medication Administration Error Variance" shall mean ~~that a drug was not given in the right amount, in the right strength, at the right time, by the correct route or methods of administration, or to the right individual. Medication administration error shall also mean that a medication was ordered and not administered~~ occur at mean 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).

- (11) ~~"Non-injectable medications" shall mean any medication that is not administered by the intradermal, subcutaneous, intramuscular or intravenous route. This includes medications that are prepackaged and premeasured for oral medication, medications administered through gastrostomy and jejunostomy feeding tubes, prescribed topical, otic, nasal, inhaled medications, ophthalmic medications, and rectal and vaginal suppository medications.~~
- (10)(12) ~~"Injectable Medications" shall mean allowed injectable medications which are only to include those medications given routinely by an injectable method to assure the continuation of a state of well-being. These medications are limited to a person requiring insulin injections on a daily basis or one time administration of life saving injections, such as EpiPens for severe allergies 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) that are pre-drawn/prepared by the pharmacy and ordered on a regular basis (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.~~
- (13) ~~"Licensed Professional Nurse" shall mean a registered professional nurse who is licensed by the State of Tennessee.~~
- (11)(14) "Monitoring" shall mean periodic review, observation, direction, and evaluation of an a certified unlicensed individual's 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)(15) ~~"Program coordinator RN Trainer" shall mean the licensed professional a registered nurse in charge of the holding an unencumbered license in the State of Tennessee and who is trained by the Department to provide medication administration training program in accordance with the curriculum and these rules.~~
- (4) (14)(16) "A p Person (receiving services)" shall mean any person with mental retardation intellectual and/or developmental disabilities ~~residing in residential settings or any adult day program funded by the Division of Mental Retardation Services~~ 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 and/or developmental disabilities, including persons served in the CHOICES program.
- (15)(17) "Provider Agency" shall mean a private non-profit or for-profit entity ~~licensed by or under agreement/contract with the State Department to provide services to individuals with mental retardation~~ intellectual/ and/or developmental disabilities.
- (18) ~~"Residential settings" shall mean any program licensed by or contracting with the Division to provide residential services to children or adults with mental retardation. Such services include supported living environments, group homes, and family based residential programs as defined in the Division of Mental Retardation's Operations Manual.~~
- (19) ~~"Supervision" shall mean the initial, as well as subsequent, verification of an unlicensed person's knowledge and skills in the performance of a specific function, as well as during training activities provided for in these rules.~~

- (20) ~~“Two year medication examination” shall mean the examination administered by the Department or its designee every two years to unlicensed staff approved to administer medications.~~
- (21) ~~“Unlicensed personnel authorized to administer medications” shall mean a person who~~
- ~~(a) is at least eighteen years of age~~
 - ~~(b) has not been convicted of a crime rationally related to his or her employment,~~
 - ~~(c) speaks, reads, writes and understands the English Language,~~
 - ~~(d) has successfully completed an approved medication administration training program,~~
 - ~~(e) is approved to administer medications by both the Department and the provider agency by which the unlicensed personnel is employed, and~~
 - ~~(f) maintains such approved status according to the provisions of these rules.~~
- (22) ~~“Testing entity” shall mean an agency or individual selected by the Department to administer medication administration competency tests, upon completion of a medication administration training program.~~
- (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.
November 4, 1998.

0465-01-03-.031200-20-12-02 Medication Administration Training Program

- (1) ~~Approval of Training Programs~~
- ~~(a) In cooperation with appropriate agencies or advisory bodies, the Department shall develop or approve initial training curricula and competency evaluation procedures for those unlicensed personnel who administer medications. A qualified testing entity or educational institution may apply to the Department for approval to conduct a Medication Administration Training Program. Upon approval of the curriculum, the Department or its designee may contract with a private provider or instructor to provide such training and administer such competency testing. The Department shall maintain a list of approved medication administration contractors for training.~~
 - ~~(b) Requests for the approval of a medication administration training program shall be submitted to the Department and include the following:~~
 - ~~1. name, address and telephone number of the agency offering the program;~~
 - ~~2. the program coordinator’s name, address, RN license number, and verification of a minimum of two years experience, at least one of which must be in the provision of services to people with developmental disabilities and mental retardation;~~
 - ~~3. statement of course objectives;~~
 - ~~4. description of course content specifying the number of hours and key topics to be~~

5. ~~a test which measures competency through a practical demonstration of the required skill;~~
~~and~~

6. ~~a written test to reflect and measure the skills and requirements of these rules.~~

(e) ~~The Department must respond to a request for approval of a medication administration training program with either a notice of the action taken or a request for additional information within 90 days of the receipt of the application for medication administration course approval.~~

(1)(2) ~~Course Content~~ Medication Administration Curriculum developed and administered by the Department.

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

(a) ~~introduction to pharmacology;~~

(a)(b) Legal and ethical aspects of medication administration;

(b)(e) State and federal regulations regarding medications;

(c)(d) Terminology, abbreviations and measurements;

(d)(e) Administration of medications;

(e)(f) Types of medications, ~~their~~ indications, actions, interactions, potential side effects, adverse reactions, and appropriate emergency response;

(f)(g) Documentation ~~and record-keeping;~~ and

(g)(h) Storage ~~and disposal~~ of medications

(2)(3) ~~Instructors~~ Certified RN Trainers

(a) The instruction of medication administration must be performed by a licensed ~~professional~~ Registered Nurse licensed and registered in the State of Tennessee ~~and who has:~~

(1) ~~who possesses~~ A minimum of two (2) years of RN experience;

(2) A minimum ~~at least of one (1) year experience of which must be~~ in the provision of services to people within the DIDD ~~mental retardation/developmental disabilities~~ system; and

(3) ~~Training personnel who may supplement the program coordinator including, but not limited to, physicians, licensed practical nurse, pharmacists, and developmental disability administrators which are subject to these rules. Supplemental training personnel must have at least two (2) years of experience in their respective fields. Experience as a direct supervisor responsible for oversight and management of staff.~~

(b) RN Trainer ~~must~~ shall 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~~ shall 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. The RN Trainer's authority to provide training in Medication Administration for~~

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Unlicensed Personnel may be terminated by the Department for failure to conform and perform to the standards set forth in these rules and the curriculum. Notice shall be provided to the RN Trainer by certified mail and he/she shall have the right to request an appeal hearing of the decision to terminate his/her authority to provide training, pursuant to the Tennessee Uniform Administrative Procedures Act.

~~(3)(4) Review of Courses (a) The Department shall have the authority to review and grant approval of medication administration training programs. It is expected that the training program will keep abreast of current standards and practices in the field and update the program accordingly.~~

~~(4)(5) Competency Based Medication Administration Training Program; Implementation~~

- ~~(a) The Department shall assure ensure that training sessions, each to be followed by a competency test set to measure basic competency, are offered at various geographic locations in the state held in accordance with these rules;~~
- ~~(b) Approved providers of medication administration training programs must have and maintain procedures for administration, security and validation of tests, and the reporting of scores results to the Department. Such procedures must include limitations of the number of times a particular test will be used. A pool of questions may be used to develop alternative tests. Provider agencies must shall develop and maintain a system for ensuring that any staff certified personnel administering medications have current certification in Medication Administration for Unlicensed Personnel;~~
- ~~(c) Each private training contractor shall provide the Department with a list of all persons who have taken an approved training session and has successfully completed a competency test. Such contractor shall also provide the Department with any other pertinent information reasonably requested by the Department. The Department will shall maintain course material for one (1) year and participant records indefinitely for five (5) years; and~~
- ~~(d) Course attendance records must be maintained for a minimum of two years from the date of completion of the course and are subject to review by the Department upon request. The Department will shall provide the agency with a participant record for each participant registered for class.~~
- ~~(e) At least 30 days before each occasion on which an approved course is to begin, sponsors of approved courses must provide written notice to the Department of the dates and location a course will be held. Medication administration training programs are subject to periodic on-site review by the Department.~~
- ~~(f) The program coordinator shall be responsible for the completion, signing, and submission to the Department of all required documentation. A coordinator shall be responsible for ensuring that the following requirements are met:
 - ~~1. course objectives are accomplished;~~
 - ~~2. only persons having appropriate skills and knowledge are selected to conduct any part of the training;~~
 - ~~3. each trainee demonstrates competence in medication administration through passing a written test and a practical demonstration of skills;~~
 - ~~4. records are kept to verify the participation and performance of each trainee in each phase of the training program, the satisfactory completion of the training program by each trainee to be attested on each trainee's record, and~~
 - ~~5. issue each trainee a letter of completion. Successful completion shall be documented by a letter provided to the employee and to the provider agency where the person is employed;~~~~

and signed by the program coordinator for the course. Such letter must contain:

- (i) the name and current address of the employee;
- (ii) title of the course;
- (iii) the employee's date of birth and social security number;
- (iv) the name(s) of the course instructor(s) and educational sponsor for the course;
- (v) the provider agency with whom the person is employed or to be employed;
- (vi) the date of successful completion of the course; and
- (vii) provide a copy of the letter to the Department.

(6) Reporting of Competency Testing

- (a) Any testing entity that administers competency testing's shall maintain a list of those who have successfully completed a competency test and shall forward a copy of such list to the provider and/or the approved training program within thirty (30) days of administration of such tests. Such testing entity shall provide additional information as required by the Department by contract with the testing entity.

(7) Denial, Suspension or Revocation of Approval to Provide Training in Medication Administration

- (a) The Department shall deny, suspend, or revoke its approval of a Medication Administration Training Program for failure by the training entity to meet the requirements of this rule 1200-20-12-.02 (i.e., Approval of Training Program). Any denial, suspension, or revocation may be appealed in writing to the Commissioner of the Department of Health. Subsequent appeals shall be made pursuant to the Rules of the Department of Finance and Administration for the purchase of services and the applicable statutes.

- (8) When required by a court order or settlement, documents and information relevant to such order or settlement may be reviewed by other appropriate individuals related to the litigation.

Authority: T.C.A. §§4-5-202, 4-5-301, 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.

November 4, 1998.

0465-01-03-.041200-20-12-.03 APPROVAL OF UNLICENSED PERSONNEL Approval of Unlicensed Personnel

- (1) Any contracted DIDD provider agency employeing staff who is are not otherwise authorized by law to administer medications in a mental retardation program shall be allowed to perform such duties only after passing a competency testing. An employee Certified personnel who administers medications in a program in complianee 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 shall satisfactorily successfully complete a the a medication administration training program which shall consisting of not less than twenty (20) hours of classroom instruction as set forth in 1200-20-12-.02(2) these rules.
- (3) To successfully complete a medication administration training program, an unlicensed employee must shall achieve a score of at least 80% percent (%) 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 shall also required and shall be determined by the program coordinator

administering the course with a score of at least 80 percent (%).

- (4) Certification must be renewed every three (3) years by:
 - (a) Successfully completing the Medication Administration for Unlicensed Personnel program; or
 - (b) Test-out; by completion of online review followed by successfully passing the written and practical tests administered by the Department a certified RN Trainer.

- (5)(4) ~~An employee will be eligible to take the competency test two times 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 in such second during the third test, the employee cannot take the test course again, nor shall the employee be allowed to administer medications. DIDD shall allow employees who failed under the previous system to start fresh under the new system. DIDD shall remove any limit on the number of times an employee may take the exam with no waiting period between attempts. After the second failure of the employee to pass the examination, the cost of further testing shall be shifted to the provider.~~

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.
~~November 4, 1998.~~

0465-01-03-.051200-20-12-.04 APPROVALS CERTIFICATION OF UNLICENSED PERSONNEL Certification of Unlicensed Personnel

- (1) ~~When a new unlicensed employee with prior medication administration training requests to administer medications in a program licensed by or under contract with the Division of Mental Retardation Services, t~~ The provider agency shall obtain confirmation proof of certification (participant record) for new employees from the Department of an employee's approval status, including the date the employee was approved, before the new employee can they are allowed to administer medications.
- (2) The Department shall verify an employee's current status and date of last successful completion of the medication administration training program.
- (3) ~~When requested, a provider agency shall notify the Department in writing whenever an approved unlicensed employee has his or her approval to administer medication withdrawn by a provider agency.~~
- (4) ~~An unlicensed employee shall not be approved if such employee:~~
 - (a) ~~is less than eighteen years of age;~~
 - (b) ~~has been convicted of a crime rationally related to his or her employment;~~
 - (c) ~~has not successfully completed an approved medication administration course;~~
 - (d) ~~received a grade below 80% for an approved medication administration course;~~
 - (e) ~~has not been approved by the provider agency to administer medications;~~
 - (f) ~~has failed to be re-tested every two years on medication administration in accordance with these rules;~~
 - (g) ~~has failed to retake the medication administration test when such individual has been previously approved to administer medications but has not worked with people with mental retardation/developmental disabilities for a period of six months; or~~
 - (h) ~~commits medication administration errors which demonstrate lack of competence.~~

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.
~~November 4, 1998.~~

~~0465-01-03-.06~~~~1200-20-12-.05~~ **LIMITATIONS ON FUNCTIONS OF UNLICENSED PERSONNEL** Limitations of Functions of Unlicensed Personnel

- (1) The following ~~procedures~~ may ~~not~~ be performed by ~~unlicensed~~certified personnel under the scope of these regulations and in accordance with the training curriculum:
 - (a) ~~endotracheal suctioning~~ Medication administration via the following routes; ~~oral, rectal, vaginal, eye, ear, nasal and topical; and.~~
 - (b) ~~urinary catheter insertion~~ Administration of medications by subcutaneous route for routine insulin (with additional training) and injectable epinephrine (i.e. EpiPen).
 - (c) ~~nasogastric tube care;~~
 - (d) ~~intravenous therapy;~~
 - (e) ~~adjustment of doses of medications;~~
 - (f) ~~tracheotomy care;~~
 - (g) ~~administration of oxygen;~~
 - (h) ~~administration of fluxuating or mixing insulin dosages; and~~
 - (i) ~~administration of medications by subcutaneous, intramuscular, intradermal or intravenous route, except for routine insulin and one time life saving injections, such as EpiPens.~~
- (2) This regulation does not preclude the performance of procedures by ~~unlicensed~~certified 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.
~~November 4, 1998.~~

~~0465-01-03.07~~~~1200-20-12-.06~~ **PROVIDER AGENCY REQUIREMENTS** Provider Agency Requirements

- (1) A provider agency ~~or program~~ employing ~~unlicensed~~certified personnel ~~must~~shall have a written policy and procedure demonstrating compliance with these rules ~~for any employees who administers medications. These~~ This policies and procedures ~~must~~shall be ~~approved~~ accepted by the Department ~~prior to the implementation of medication administration by unlicensed employees in that provider agency or program~~ and ~~must~~shall include, at a minimum, the following elements:
 - (a) Medication Prohibitions;
 - (b) Security;
 - (c) Program ~~r~~Requirements;
 - (d) Medication ~~s~~Storage and ~~l~~Labeling;

- (e) ~~Editing of Medication-medication Recordsrecords;~~
 - (f) ~~Medication rRefusal;~~
 - (g) Medication Administration Record (MAR);
 - (h) ~~Controlled sSubstances;~~
 - (i) ~~Medication vVariances;~~
 - (j) ~~Medication dDisposal;~~
 - (k) ~~Family vVisit; and~~
 - (l) ~~Self-Administration.~~
- (2) A provider agency ~~must~~ shall have a separate Medication Administration Record (MAR) of ordered medications for each person ~~receiving medication~~. The record ~~documenting administration~~ 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, ~~ordering, or approving~~ practitioner;
 - (e) ~~s~~Starts date and stop dates, if applicable; and
 - (f) ~~expected therapeutic effects for the person taking the medication~~ Any specific directions;
 - (g) ~~possible side effects to the person taking the medication;~~
 - (h) ~~storage of medications; and~~
 - (i) ~~disposal of medications~~
- (3) ~~As a condition to authorizing or renewing the authorization to operate any provider agency or program that administers medications to persons with mental retardation/developmental disabilities, the Division shall require that the agency have employees qualified pursuant to these rules on duty at any time that the agency administers such medications. The agency must maintain a written record of each medication administered to each person. Such record will be subject to review by the Division as a part of its procedure in authorizing the continued operation of the provider agency and the provider agency's programs.~~ A provider agency ~~must~~ shall 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~~ shall be maintained in accordance with State and Federal laws and DIDD regulations.
- (5) The agency must have certified ~~staff personnel~~ available to administer medications as ordered and at a place convenient for the person.

~~0465-01-03-.081200-20-12-.07~~ SUSPENSION TERMINATION OF AUTHORITY TO ADMINISTER-
MEDICATION 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~~ personnel 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 ~~services in the administration of~~ medications; or
 - (c) Failure to conform to the essential ~~standards~~ 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~~ certified personnel by certified mail and he/she shall have the right to request an appeal hearing on his/her termination of authority to administer medications, pursuant to the Tennessee Uniform Administrative Procedures Act.

- ~~(2) Any such denial or suspension of the unlicensed employee's authority shall be reported to the Department in writing. 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, 4-5-301, 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.

~~November 4, 1998.~~

~~0465-01-03-.091200-20-12-.08~~ MONITORING OF UNLICENSED PERSONNEL Monitoring of Unlicensed Personnel

- (1) The Department ~~will~~ shall monitor the administration of medications by unlicensed ~~employees~~ personnel. ~~through quality enhancement surveys and follow-up m~~ Monitoring ~~will~~ shall be completed by Registered Nurses employed by ~~or contracted with~~ the Department.
- (2) ~~Regarding medication administration, monitoring shall include, but not be limited to, review of each provider agency's evaluation and performance records for unlicensed employees who perform the functions and activities provided for in these rules. Such records shall encompass statements and observations by supervisors of unlicensed personnel made during the course of the work performed by the unlicensed employees. Monitoring may include direct observation of medication administration by unlicensed employees approved pursuant to these rules. The provider agency will~~ shall monitor, at a minimum, the first medication pass of the unlicensed personnel upon successful completion of their his/her 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.

~~November 4, 1998.~~

RULES
 OF
 TENNESSEE DEPARTMENT OF HEALTH
 INTELLECTUAL AND DEVELOPMENTAL
 DISABILITIES

~~CHAPTER 1200-20-12~~
 0465-01-03
 ADMINISTRATION OF MEDICATION BY UNLICENSED PERSONNEL
 TO PEOPLE WITH MENTAL RETARDATION

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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 ~~1200-20-12-.01~~ DEFINITIONS: As used in these rules, the terms below shall have the following meanings ascribed to them.

- (1) "Administration of medications~~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 attending physician prescribing practitioner; ~~or other authorized practitioner or as written on the prescription label~~ and making a written record thereof with regard to each medication administered, including the time and amount taken, ~~but a Administration does not include judgment, evaluation or assessment.~~
- (2) ~~"Adult day programs" shall mean any program licensed or contracted by the Division of Mental Retardation Services to provide day activities to people with mental retardation over eighteen years of age. Such services include day habilitation, follow-along, supported employment and community participation.~~
- (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:

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- (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, ~~wright-write~~ and communicate verbally in English ~~and as well as 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 provisions of these rules.
- (4)(3) "Competency testing" shall mean a written ~~exam~~ examination and a practical demonstration of skills that measure basic ~~competency~~ proficiency in medication administration.
- (4) ~~"The Board" shall mean the Tennessee Board of Nursing~~
- (5) "Curriculum" shall mean ~~a detailed course outline, description or syllabus submitted to the Department as part of the approval process of an entity, nursing agency, health care facility or Division sponsoring a medication administration course. At a minimum, a curriculum for approval or re-approval shall contain the following:~~ the current course training program 'Medication Administration for Unlicensed Personnel'.
- (a) ~~title~~
 - (b) ~~names and authors~~
 - (c) ~~specific course objectives~~
 - (d) ~~units to be covered in the course~~
 - (e) ~~hours to be spent in each unit~~
 - (f) ~~the methods of instruction~~
 - (g) ~~a description of the practical training to be provided~~
 - (h) ~~a written test to measure competency in medication administration; and~~
 - (i) ~~a description of a test to measure competency through a practical demonstration of each required skill~~
- (6) "Department" shall mean the Tennessee Department of ~~Health~~ Intellectual and Developmental Disabilities, also referred to as DIDD.
- (7) ~~"Division" shall mean the Division of Mental Retardation Services of the Department of Mental Health and Mental Retardation.~~
- (7)(8) "Drugs or Medications" shall mean substances intended for use in diagnosis, care, mitigations, treatment, or prevention.
- (8)(9) "Employee" shall mean an individual who is unlicensed and is employed ~~by~~ or receives payment through a provider agency contracting with the Department.
- (9)(10) "Medication Administration Error Variance" shall mean ~~that a drug was not given in the right amount, in the right strength, at the right time, by the correct route or methods of administration, or to the right individual. Medication administration error shall also mean that a medication was ordered and not administered~~ occur at mean any time a medication is given in a way that is inconsistent with how it was

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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).

- (11) ~~"Non-injectable medications" shall mean any medication that is not administered by the intradermal, subcutaneous, intramuscular or intravenous route. This includes medications that are prepackaged and premeasured for oral medication, medications administered through gastrostomy and jejunostomy feeding tubes, prescribed topical, otic, nasal, inhaled medications, ophthalmic medications, and rectal and vaginal suppository medications.~~
- (10)(12) ~~"Injectable Medications" shall mean allowed injectable medications which are only to include those medications given routinely by an injectable method to assure the continuation of a state of well-being. These medications are limited to a person requiring insulin injections on a daily basis or one time administration of life saving injections, such as EpiPens for severe allergies 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) that are pre-drawn/prepared by the pharmacy and ordered on a regular basis (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.~~
- (13) ~~"Licensed Professional Nurse" shall mean a registered professional nurse who is licensed by the State of Tennessee.~~
- (11)(14) ~~"Monitoring" shall mean periodic review, observation, direction, and evaluation of an a certified unlicensed individual's 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)(15) ~~"Program coordinator RN Trainer" shall mean the licensed professional a registered nurse in charge of the holding an unencumbered license in the State of Tennessee and who is trained by the Department to provide medication administration training program in accordance with the curriculum and these rules.~~
- (4) (14)(16) ~~"A p Person (receiving services)" shall mean any person with mental retardation intellectual and/or developmental disabilities residing in residential settings or any adult day program funded by the Division of Mental Retardation Services 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 and/or developmental disabilities, including persons served in the CHOICES program.~~
- (15)(17) ~~"Provider Agency" shall mean a private non-profit or for-profit entity licensed by or under agreement/contract with the State Department to provide services to individuals with mental retardation intellectual/ and/or developmental disabilities.~~
- (18) ~~"Residential settings" shall mean any program licensed by or contracting with the Division to provide residential services to children or adults with mental retardation. Such services include supported living environments, group homes, and family based residential programs as defined in the Division of Mental Retardation's Operations Manual.~~
- (19) ~~"Supervision" shall mean the initial, as well as subsequent, verification of an unlicensed person's knowledge and skills in the performance of a specific function, as well as during training activities provided for in these rules.~~

- (20) ~~“Two year medication examination” shall mean the examination administered by the Department or its designee every two years to unlicensed staff approved to administer medications.~~
- (21) ~~“Unlicensed personnel authorized to administer medications” shall mean a person who~~
- ~~(a) is at least eighteen years of age~~
 - ~~(b) has not been convicted of a crime rationally related to his or her employment;~~
 - ~~(c) speaks, reads, writes and understands the English Language;~~
 - ~~(d) has successfully completed an approved medication administration training program;~~
 - ~~(e) is approved to administer medications by both the Department and the provider agency by which the unlicensed personnel is employed, and~~
 - ~~(f) maintains such approved status according to the provisions of these rules.~~
- (22) ~~“Testing entity” shall mean an agency or individual selected by the Department to administer medication administration competency tests, upon completion of a medication administration training program.~~
- (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.
November 4, 1998.

0465-01-03-.031200-20-12-02- Medication Administration Training Program

- (1) ~~Approval of Training Programs~~
- ~~(a) In cooperation with appropriate agencies or advisory bodies, the Department shall develop or approve initial training curricula and competency evaluation procedures for those unlicensed personnel who administer medications. A qualified testing entity or educational institution may apply to the Department for approval to conduct a Medication Administration Training Program. Upon approval of the curriculum, the Department or its designee may contract with a private provider or instructor to provide such training and administer such competency testing. The Department shall maintain a list of approved medication administration contractors for training.~~
 - ~~(b) Requests for the approval of a medication administration training program shall be submitted to the Department and include the following:~~
 - ~~1. name, address and telephone number of the agency offering the program;~~
 - ~~2. the program coordinator's name, address, RN license number, and verification of a minimum of two years experience, at least one of which must be in the provision of services to people with developmental disabilities and mental retardation;~~
 - ~~3. statement of course objectives;~~
 - ~~4. description of course content specifying the number of hours and key topics to be~~

5. ~~a test which measures competency through a practical demonstration of the required skill;~~
and

6. ~~a written test to reflect and measure the skills and requirements of these rules.~~

(e) ~~The Department must respond to a request for approval of a medication administration training program with either a notice of the action taken or a request for additional information within 90 days of the receipt of the application for medication administration course approval.~~

(1)(2) ~~Course Content~~ Medication Administration Curriculum developed and administered by the Department.

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

(a) ~~introduction to pharmacology;~~

(a)(b) Legal and ethical aspects of medication administration;

(b)(e) State and federal regulations regarding medications;

(c)(d) Terminology, abbreviations and measurements;

(d)(e) Administration of medications;

(e)(f) Types of medications, ~~their~~ indications, actions, interactions, potential side effects, adverse reactions, and appropriate emergency response;

(f)(g) Documentation ~~and record-keeping;~~ and

(g)(h) Storage ~~and disposal~~ of medications

(2)(3) ~~Instructors~~ Certified RN Trainers

(a) The instruction of medication administration must be performed by a ~~licensed professional Registered Nurse~~ licensed and registered in the State of Tennessee ~~and who~~ has:

(1) ~~who possesses~~ A minimum of two (2) years of RN experience;

(2) A minimum ~~at least of one (1) year experience of which must be in the provision of services to people within the DIDD mental retardation/developmental disabilities system;~~
and

(3) ~~Training personnel who may supplement the program coordinator including, but not limited to, physicians, licensed practical nurse, pharmacists, and developmental disability administrators which are subject to these rules. Supplemental training personnel must have at least two (2) years of experience in their respective fields. Experience as a direct supervisor responsible for oversight and management of staff.~~

(b) RN Trainer ~~must shall~~ 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 shall~~ 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. The RN Trainer's authority to provide training in Medication Administration for~~

Unlicensed Personnel may be terminated by the Department for failure to conform and perform to the standards set forth in these rules and the curriculum. Notice shall be provided to the RN Trainer by certified mail and he/she shall have the right to request an appeal hearing of the decision to terminate his/her authority to provide training, pursuant to the Tennessee Uniform Administrative Procedures Act.

~~(3)(4) Review of Courses (a) The Department shall have the authority to review and grant approval of medication administration training programs. It is expected shall that the training program will to keep abreast of current standards and practices in the field and update the program accordingly.~~

~~(4)(5) Competency Based Medication Administration Training Program: Implementation~~

- ~~(a) The Department shall assure ensure that training sessions, each to be followed by a competency test set to measure basic competency, are offered at various geographic locations in the state held in accordance with these rules;:-~~
- ~~(b) Approved providers of medication administration training programs must have and maintain procedures for administration, security and validation of tests, and the reporting of scores results to the Department. Such procedures must include limitations of the number of times a particular test will be used. A pool of questions may be used to develop alternative tests. Provider agencies must shall develop and maintain a system for ensuring that any staff certified personnel administering medications have current certification in Medication Administration for Unlicensed Personnel;:-~~
- ~~(c) Each private training contractor shall provide the Department with a list of all persons who have taken an approved training session and has successfully completed a competency test. Such contractor shall also provide the Department with any other pertinent information reasonably requested by the Department. The Department will shall maintain course material for one (1) year and participant records indefinitely for five (5) years;:- and~~
- ~~(d) Course attendance records must be maintained for a minimum of two years from the date of completion of the course and are subject to review by the Department upon request. The Department will shall provide the agency with a participant record for each participant registered for class.~~
- ~~(e) At least 30 days before each occasion on which an approved course is to begin, sponsors of approved courses must provide written notice to the Department of the dates and location a course will be held. Medication administration training programs are subject to periodic on-site review by the Department.~~
- ~~(f) The program coordinator shall be responsible for the completion, signing, and submission to the Department of all required documentation. A coordinator shall be responsible for ensuring that the following requirements are met:
 - 1. ~~course objectives are accomplished;~~
 - 2. ~~only persons having appropriate skills and knowledge are selected to conduct any part of the training;~~
 - 3. ~~each trainee demonstrates competence in medication administration through passing a written test and a practical demonstration of skills;~~
 - 4. ~~records are kept to verify the participation and performance of each trainee in each phase of the training program, the satisfactory completion of the training program by each trainee to be attested on each trainee's record, and~~
 - 5. ~~issue each trainee a letter of completion. Successful completion shall be documented by a letter provided to the employee and to the provider agency where the person is employed;~~~~

and signed by the program coordinator for the course. Such letter must contain:

- (i) the name and current address of the employee;
- (ii) title of the course;
- (iii) the employee's date of birth and social security number;
- (iv) the name(s) of the course instructor(s) and educational sponsor for the course;
- (v) the provider agency with whom the person is employed or to be employed;
- (vi) the date of successful completion of the course; and
- (vii) provide a copy of the letter to the Department.

(6) Reporting of Competency Testing

- (a) Any testing entity that administers competency testing's shall maintain a list of those who have successfully completed a competency test and shall forward a copy of such list to the provider and/or the approved training program within thirty (30) days of administration of such tests. Such testing entity shall provide additional information as required by the Department by contract with the testing entity.

(7) Denial, Suspension or Revocation of Approval to Provide Training in Medication Administration

- (a) The Department shall deny, suspend, or revoke its approval of a Medication Administration Training Program for failure by the training entity to meet the requirements of this rule 1200-20-12.02 (i.e., Approval of Training Program). Any denial, suspension, or revocation may be appealed in writing to the Commissioner of the Department of Health. Subsequent appeals shall be made pursuant to the Rules of the Department of Finance and Administration for the purchase of services and the applicable statutes.

- (8) When required by a court order or settlement, documents and information relevant to such order or settlement may be reviewed by other appropriate individuals related to the litigation.

Authority: T.C.A. §§4-5-202, 4-5-301, 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.

November 4, 1998.

0465-01-03-.041200-20-12-.03 APPROVAL OF UNLICENSED PERSONNEL Approval of Unlicensed Personnel

- (1) Any contracted DIDD provider agency employe~~ing~~ staff who is are not otherwise authorized by law to administer medications in a mental retardation program shall be allowed to perform such duties only after passing a competency testing. An employee Certified personnel who administers medications in a program in complian~~ee~~ 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 ~~shall satisfactorily~~ successfully complete a the a medication administration training program which ~~shall~~ consisting of not less than twenty (20) hours of classroom instruction as set forth in ~~1200-20-12.02(2)~~ these rules.
- (3) To successfully complete a medication administration training program, an unlicensed employee ~~must~~ shall achieve a score of at least 80% percent (%) 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 shall also required and ~~shall be determined by the program coordinator~~

administering the course with a score of at least 80 percent (%).

- (4) Certification must be renewed every three (3) years by:
 - (a) Successfully completing the Medication Administration for Unlicensed Personnel program; or
 - (b) Test-out; by completion of online review followed by successfully passing the written and practical tests administered by the Departmenta certified RN Trainer.
- (5)(4) ~~An employee will be eligible to take the competency test two times 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 in such second during the third test, the employee cannot take the test course again, nor shall the employee be allowed to administer medications. DIDD shall allow employees who failed under the previous system to start fresh under the new system. DIDD shall remove any limit on the number of times an employee may take the exam with no waiting period between attempts. After the second failure of the employee to pass the examination, the cost of further testing shall be shifted to the provider.~~

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.
~~November 4, 1998.~~

0465-01-03-.051200-20-12-.04 APPROVALS CERTIFICATION OF UNLICENSED PERSONNEL Certification of Unlicensed Personnel

- (1) ~~When a new unlicensed employee with prior medication administration training requests to administer medications in a program licensed by or under contract with the Division of Mental Retardation Services, t~~ The provider agency shall obtain confirmation proof of certification (participant record) for new employees from the Department of ~~an employee's approval status, including the date the employee was approved, before the new employee can~~ they are allowed to administer medications.
- (2) The Department shall verify an employee's current status and date of last successful completion of the medication administration training program.
- (3) ~~When requested, a provider agency shall notify the Department in writing whenever an approved unlicensed employee has his or her approval to administer medication withdrawn by a provider agency.~~
- (4) ~~An unlicensed employee shall not be approved if such employee:~~
 - (a) ~~is less than eighteen years of age;~~
 - (b) ~~has been convicted of a crime rationally related to his or her employment;~~
 - (c) ~~has not successfully completed an approved medication administration course;~~
 - (d) ~~received a grade below 80% for an approved medication administration course;~~
 - (e) ~~has not been approved by the provider agency to administer medications;~~
 - (f) ~~has failed to be re-tested every two years on medication administration in accordance with these rules;~~
 - (g) ~~has failed to retake the medication administration test when such individual has been previously approved to administer medications but has not worked with people with mental retardation/developmental disabilities for a period of six months; or~~
 - (h) ~~commits medication administration errors which demonstrate lack of competence.~~

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.
~~November 4, 1998.~~

0465-01-03-.061200-20-12-.05 LIMITATIONS ON FUNCTIONS OF UNLICENSED PERSONNELLimitations of Functions of Unlicensed Personnel

- (1) The following ~~procedures~~ may ~~not~~ be performed by ~~unlicensed~~certified personnel under the scope of these regulations and in accordance with the training curriculum:
 - (a) ~~endotracheal suctioning~~ Medication administration via the following routes; ~~oral, rectal, vaginal, eye, ear, nasal and topical; and~~
 - (b) ~~urinary catheter insertion~~ Administration of medications by subcutaneous route for routine insulin (with additional training) and injectable epinephrine (i.e. EpiPen).
 - (c) ~~nasogastric tube care;~~
 - (d) ~~intravenous therapy;~~
 - (e) ~~adjustment of doses of medications;~~
 - (f) ~~tracheotomy care;~~
 - (g) ~~administration of oxygen;~~
 - (h) ~~administration of fluxuating or mixing insulin dosages; and~~
 - (i) ~~administration of medications by subcutaneous, intramuscular, intradermal or intravenous route, except for routine insulin and one time life saving injections, such as EpiPens.~~
- (2) This regulation does not preclude the performance of procedures by ~~unlicensed~~certified 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.
~~November 4, 1998.~~

0465-01-03.071200-20-12-.06 PROVIDER AGENCY REQUIREMENTSProvider Agency Requirements

- (1) A provider agency ~~or program~~ employing ~~unlicensed~~certified personnel ~~must~~shall have a written policy ~~and procedure~~ demonstrating compliance with these rules ~~for any employees who administers medications. These~~ This policies and procedures ~~must~~shall be ~~approved~~ accepted by the Department prior to the implementation of medication administration by ~~unlicensed employees in that provider agency or program~~ and ~~must~~shall include, at a minimum, the following elements:
 - (a) Medication Prohibitions;
 - (b) Security;
 - (c) Program ~~r~~Requirements;
 - (d) Medication ~~s~~Storage and ~~l~~Labeling;

- (e) ~~Editing of Medication-medication Recordsrecords;~~
 - (f) Medication ~~r~~Refusal;
 - (g) Medication Administration Record (MAR);
 - (h) Controlled ~~s~~Substances;
 - (i) Medication ~~v~~Variances;
 - (j) Medication ~~d~~Disposal;
 - (k) Family ~~v~~Visit; and
 - (l) Self-Administration.
- (2) A provider agency ~~must~~shall have a separate Medication Administration Record (MAR) of ordered medications for each person ~~receiving medication~~. The record ~~documenting administration~~ 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, ~~ordering, or approving~~ practitioner;
 - (e) ~~s~~Starts date and stop dates, if applicable; and
 - (f) ~~expected therapeutic effects for the person taking the medication~~ Any specific directions;
 - (g) ~~possible side effects to the person taking the medication;~~
 - (h) ~~storage of medications; and~~
 - (i) ~~disposal of medications~~
- (3) ~~As a condition to authorizing or renewing the authorization to operate any provider agency or program that administers medications to persons with mental retardation/developmental disabilities, the Division shall require that the agency have employees qualified pursuant to these rules on duty at any time that the agency administers such medications. The agency must maintain a written record of each medication administered to each person. Such record will be subject to review by the Division as a part of its procedure in authorizing the continued operation of the provider agency and the provider agency's programs. A provider agency must~~shall 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~~shall be maintained in accordance with State and Federal laws and DIDD regulations.
- (5) The agency must have certified ~~staff personnel~~ available to administer medications as ordered and at a place convenient for the person.

~~0465-01-03-.081200-20-12-.07~~ **SUSPENSION TERMINATION OF AUTHORITY TO ADMINISTER MEDICATION**
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-personnel~~ 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 ~~services in the administration of~~ medications; or
 - (c) Failure to conform to the essential ~~standards~~ 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-certified personnel~~ by certified mail and he/she shall have the right to request an appeal hearing on his/her termination of authority to administer medications, pursuant to the Tennessee Uniform Administrative Procedures Act.

- ~~(2) Any such denial or suspension of the unlicensed employee's authority shall be reported to the Department in writing. 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, ~~4-5-301~~, 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.
~~November 4, 1998.~~

~~0465-01-03-.091200-20-12-.08~~ **MONITORING OF UNLICENSED PERSONNEL**
Monitoring of Unlicensed Personnel

- (1) The Department ~~will~~ shall monitor the administration of medications by unlicensed ~~employees~~ personnel. ~~through quality enhancement surveys and follow-up in~~ Monitoring ~~will~~ shall be completed by Registered Nurses employed by ~~or contracted with~~ the Department.
- (2) ~~Regarding medication administration, monitoring shall include, but not be limited to, review of each provider agency's evaluation and performance records for unlicensed employees who perform the functions and activities provided for in these rules. Such records shall encompass statements and observations by supervisors of unlicensed personnel made during the course of the work performed by the unlicensed employees. Monitoring may include direct observation of medication administration by unlicensed employees approved pursuant to these rules. The provider agency will~~ shall monitor, at a minimum, the first medication pass of the unlicensed personnel upon successful completion of their his/her 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.
~~November 4, 1998.~~

**RULES
 OF
 TENNESSEE DEPARTMENT OF HEALTH-
 INTELLECTUAL AND DEVELOPMENTAL
 DISABILITIES**

**CHAPTER ~~1200-20-12~~
 0465-01-03
 ADMINISTRATION OF MEDICATION BY UNLICENSED PERSONNEL
 TO PEOPLE WITH MENTAL RETARDATION**

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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 ~~1200-20-12-.01~~ DEFINITIONS: As used in these rules, the terms below shall have the following meanings ascribed to them.

- (1) "Administration of ~~medications~~ 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 ~~attending physician~~ prescribing practitioner; ~~or other authorized practitioner~~ or as written on the prescription label and making a written record thereof with regard to each medication administered, including the time and amount taken, ~~but a Administration does not include judgment, evaluation or assessment.~~
- ~~(2) "Adult day programs" shall mean any program licensed or contracted by the Division of Mental Retardation Services to provide day activities to people with mental retardation over eighteen years of age. Such services include day habilitation, follow along, supported employment and community participation.~~
- (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:

ADMINISTRATION OF MEDICATION BY UNLICENSED PERSONNEL CHAPTER 0465-01-03 1200-20-12
~~TO PEOPLE WITH MENTAL RETARDATION~~

- (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, ~~wright~~-write and communicate verbally in English ~~and as well as 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 provisions of these rules.
- (4)(3) "Competency testing" shall mean a written ~~exam~~ examination and a practical demonstration of skills that measure basic ~~competency~~ proficiency in medication administration.
- ~~(4) "The Board" shall mean the Tennessee Board of Nursing~~
- (5) "Curriculum" shall mean ~~a detailed course outline, description or syllabus submitted to the Department as part of the approval process of an entity, nursing agency, health care facility or Division sponsoring a medication administration course. At a minimum, a curriculum for approval or re-approval shall contain the following:~~ the current course training program 'Medication Administration for Unlicensed Personnel'.
- ~~(a) title~~
 - ~~(b) names and authors~~
 - ~~(c) specific course objectives~~
 - ~~(d) units to be covered in the course~~
 - ~~(e) hours to be spent in each unit~~
 - ~~(f) the methods of instruction~~
 - ~~(g) a description of the practical training to be provided~~
 - ~~(h) a written test to measure competency in medication administration; and~~
 - ~~(i) a description of a test to measure competency through a practical demonstration of each required skill~~
- (6) "Department" shall mean the Tennessee Department of ~~Health~~ Intellectual and Developmental Disabilities, also referred to as DIDD.
- ~~(7) "Division" shall mean the Division of Mental Retardation Services of the Department of Mental Health and Mental Retardation.~~
- (7)(8) "Drugs or Medications" shall mean substances intended for use in diagnosis, care, mitigations, treatment, or prevention.
- (8)(9) "Employee" shall mean an individual who is unlicensed and is employed ~~by~~ or receives payment through a provider agency contracting with the Department.
- (9)(10) "Medication Administration Error Variance" shall ~~mean that a drug was not given in the right amount, in the right strength, at the right time, by the correct route or methods of administration, or to the right individual. Medication administration error shall also mean that a medication was ordered and not administered~~ 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).

- (11) ~~"Non-injectable medications" shall mean any medication that is not administered by the intradermal, subcutaneous, intramuscular or intravenous route. This includes medications that are prepackaged and premeasured for oral medication, medications administered through gastrostomy and jejunostomy feeding tubes, prescribed topical, otic, nasal, inhaled medications, ophthalmic medications, and rectal and vaginal suppository medications.~~
- (10)(12) ~~"Injectable Medications" shall mean allowed injectable medications which are only to include those medications given routinely by an injectable method to assure the continuation of a state of well-being. These medications are limited to a person requiring insulin injections on a daily basis or one time administration of life saving injections, such as EpiPens for severe allergies 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) that are pre-drawn/prepared by the pharmacy and ordered on a regular basis (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.~~
- (13) ~~"Licensed Professional Nurse" shall mean a registered professional nurse who is licensed by the State of Tennessee.~~
- (11)(14) ~~"Monitoring" shall mean periodic review, observation, direction, and evaluation of an a certified unlicensed individual's 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)(15) ~~"Program coordinator RN Trainer" shall mean the licensed professional a registered nurse in charge of the holding an unencumbered license in the State of Tennessee and who is trained by the Department to provide medication administration training program in accordance with the curriculum and these rules.~~
- (4) (14)(16) ~~"A p Person (receiving services)" shall mean any person with mental retardation intellectual and/or developmental disabilities residing in residential settings or any adult day program funded by the Division of Mental Retardation Services 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 and/or developmental disabilities, including persons served in the CHOICES program.~~
- (15)(17) ~~"Provider Agency" shall mean a private non-profit or for-profit entity licensed by or under agreement/contract with the State Department to provide services to individuals with mental retardation intellectual/ and/or developmental disabilities.~~
- (18) ~~"Residential settings" shall mean any program licensed by or contracting with the Division to provide residential services to children or adults with mental retardation. Such services include supported living environments, group homes, and family based residential programs as defined in the Division of Mental Retardation's Operations Manual.~~
- (19) ~~"Supervision" shall mean the initial, as well as subsequent, verification of an unlicensed person's knowledge and skills in the performance of a specific function, as well as during training activities provided for in these rules.~~

- (20) ~~“Two year medication examination” shall mean the examination administered by the Department or its designee every two years to unlicensed staff approved to administer medications.~~
- (21) ~~“Unlicensed personnel authorized to administer medications” shall mean a person who~~
- ~~(a) is at least eighteen years of age~~
 - ~~(b) has not been convicted of a crime rationally related to his or her employment,~~
 - ~~(c) speaks, reads, writes and understands the English Language,~~
 - ~~(d) has successfully completed an approved medication administration training program,~~
 - ~~(e) is approved to administer medications by both the Department and the provider agency by which the unlicensed personnel is employed, and~~
 - ~~(f) maintains such approved status according to the provisions of these rules.~~
- (22) ~~“Testing entity” shall mean an agency or individual selected by the Department to administer medication administration competency tests, upon completion of a medication administration training program.~~
- (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.
November 4, 1998.

0465-01-03-.031200-20-12-.02 Medication Administration Training Program

- (1) ~~Approval of Training Programs~~
- ~~(a) In cooperation with appropriate agencies or advisory bodies, the Department shall develop or approve initial training curricula and competency evaluation procedures for those unlicensed personnel who administer medications. A qualified testing entity or educational institution may apply to the Department for approval to conduct a Medication Administration Training Program. Upon approval of the curriculum, the Department or its designee may contract with a private provider or instructor to provide such training and administer such competency testing. The Department shall maintain a list of approved medication administration contractors for training.~~
 - ~~(b) Requests for the approval of a medication administration training program shall be submitted to the Department and include the following:~~
 - 1. ~~name, address and telephone number of the agency offering the program;~~
 - 2. ~~the program coordinator's name, address, RN license number, and verification of a minimum of two years experience, at least one of which must be in the provision of services to people with developmental disabilities and mental retardation;~~
 - 3. ~~statement of course objectives;~~
 - 4. ~~description of course content specifying the number of hours and key topics to be~~

5. ~~a test which measures competency through a practical demonstration of the required skill;~~
and

6. ~~a written test to reflect and measure the skills and requirements of these rules.~~

(e) ~~The Department must respond to a request for approval of a medication administration training program with either a notice of the action taken or a request for additional information within 90 days of the receipt of the application for medication administration course approval.~~

(1)(2) ~~Course Content Medication Administration Curriculum developed and administered by the Department.~~

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

(a) ~~introduction to pharmacology;~~

(a)(b) Legal and ethical aspects of medication administration;

(b)(e) State and federal regulations regarding medications;

(c)(d) Terminology, abbreviations and measurements;

(d)(e) Administration of medications;

(e)(f) Types of medications, ~~their~~ indications, actions, interactions, potential side effects, adverse reactions, and appropriate emergency response;

(f)(g) Documentation and record-keeping; and

(g)(h) Storage and disposal of medications

(2)(3) ~~Instructors Certified RN Trainers~~

(a) The instruction of medication administration must be performed by a licensed professional ~~R~~egistered ~~N~~nurse licensed and registered in the State of Tennessee and who has:

(1) ~~who possesses~~ A minimum of two (2) years of RN experience;

(2) A minimum at least of one (1) year experience ~~of which must be~~ in the provision of services to people within the DIDD ~~mental retardation/developmental disabilities~~ system; and

(3) ~~Training personnel who may supplement the program coordinator including, but not limited to, physicians, licensed practical nurse, pharmacists, and developmental disability administrators which are subject to these rules. Supplemental training personnel must have at least two (2) years of experience in their respective fields. Experience as a direct supervisor responsible for oversight and management of staff.~~

(b) RN Trainer ~~must~~ shall 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~~ shall 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. The RN Trainer's authority to provide training in Medication Administration for~~

Unlicensed Personnel may be terminated by the Department for failure to conform and perform to the standards set forth in these rules and the curriculum. Notice shall be provided to the RN Trainer by certified mail and he/she shall have the right to request an appeal hearing of the decision to terminate his/her authority to provide training, pursuant to the Tennessee Uniform Administrative Procedures Act.

~~(3)(4) Review of Courses (a) The Department shall have the authority to review and grant approval of medication administration training programs. It is expected that the training program will keep abreast of current standards and practices in the field and update the program accordingly.~~

~~(4)(5) Competency Based Medication Administration Training Program; Implementation~~

- ~~(a) The Department shall assure ensure that training sessions, each to be followed by a competency test set to measure basic competency, are offered at various geographic locations in the state held in accordance with these rules;~~
- ~~(b) Approved providers of medication administration training programs must have and maintain procedures for administration, security and validation of tests, and the reporting of scores results to the Department. Such procedures must include limitations of the number of times a particular test will be used. A pool of questions may be used to develop alternative tests. Provider agencies must shall develop and maintain a system for ensuring that any staff certified personnel administering medications has current certification in Medication Administration for Unlicensed Personnel;~~
- ~~(c) Each private training contractor shall provide the Department with a list of all persons who have taken an approved training session and has successfully completed a competency test. Such contractor shall also provide the Department with any other pertinent information reasonably requested by the Department. The Department will shall maintain course material for one (1) year and participant records indefinitely for five (5) years; and~~
- ~~(d) Course attendance records must be maintained for a minimum of two years from the date of completion of the course and are subject to review by the Department upon request. The Department will shall provide the agency with a participant record for each participant registered for class.~~
- ~~(e) At least 30 days before each occasion on which an approved course is to begin, sponsors of approved courses must provide written notice to the Department of the dates and location a course will be held. Medication administration training programs are subject to periodic on-site review by the Department.~~
- ~~(f) The program coordinator shall be responsible for the completion, signing, and submission to the Department of all required documentation. A coordinator shall be responsible for ensuring that the following requirements are met:
 - ~~1. course objectives are accomplished;~~
 - ~~2. only persons having appropriate skills and knowledge are selected to conduct any part of the training;~~
 - ~~3. each trainee demonstrates competence in medication administration through passing a written test and a practical demonstration of skills;~~
 - ~~4. records are kept to verify the participation and performance of each trainee in each phase of the training program, the satisfactory completion of the training program by each trainee to be attested on each trainee's record, and~~
 - ~~5. issue each trainee a letter of completion. Successful completion shall be documented by a letter provided to the employee and to the provider agency where the person is employed;~~~~

and signed by the program coordinator for the course. Such letter must contain:

- (i) the name and current address of the employee;
- (ii) title of the course;
- (iii) the employee's date of birth and social security number;
- (iv) the name(s) of the course instructor(s) and educational sponsor for the course;
- (v) the provider agency with whom the person is employed or to be employed;
- (vi) the date of successful completion of the course; and
- (vii) provide a copy of the letter to the Department.

(6) Reporting of Competency Testing

- (a) Any testing entity that administers competency testing's shall maintain a list of those who have successfully completed a competency test and shall forward a copy of such list to the provider and/or the approved training program within thirty (30) days of administration of such tests. Such testing entity shall provide additional information as required by the Department by contract with the testing entity.

(7) Denial, Suspension or Revocation of Approval to Provide Training in Medication Administration

- (a) The Department shall deny, suspend, or revoke its approval of a Medication Administration Training Program for failure by the training entity to meet the requirements of this rule 1200-20-12-.02 (i.e., Approval of Training Program). Any denial, suspension, or revocation may be appealed in writing to the Commissioner of the Department of Health. Subsequent appeals shall be made pursuant to the Rules of the Department of Finance and Administration for the purchase of services and the applicable statutes.

(8) When required by a court order or settlement, documents and information relevant to such order or settlement may be reviewed by other appropriate individuals related to the litigation.

Authority: T.C.A. §§4-5-202, 4-5-301, 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.

November 4, 1998.

0465-01-03-.041200-20-12-.03 APPROVAL OF UNLICENSED PERSONNEL Approval of Unlicensed Personnel

- (1) Any contracted DIDD provider agency employe~~ee~~ing staff who is are not otherwise authorized by law to administer medications in a mental retardation program shall be allowed to perform such duties only after passing a competency testing. An employe~~e~~-Certified personnel who administers medications in a program in compliance 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 employe~~e~~ must ~~shall~~ satisfactorily successfully complete a the-a medication administration training program which shall consisting of not less than twenty (20) hours of classroom instruction as set forth in 1200-20-12-.02(2) these rules.
- (3) To successfully complete a medication administration training program, an unlicensed employe~~e~~ must shall achieve a score of at least 80% percent (%) 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 ~~shall~~ also required and shall be determined by the program coordinator

administering the course with a score of at least 80 percent (%).

- (4) Certification must be renewed every three (3) years by:
 - (a) Successfully completing the Medication Administration for Unlicensed Personnel program; or
 - (b) Test-out; by completion of online review followed by successfully passing the written and practical tests administered by the Departmenta certified RN Trainer.
- (5)(4) An employee will be eligible to take the competency test two times 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 in such second during the third test, the employee cannot take the test course again, nor shall the employee be allowed to administer medications. DIDD shall allow employees who failed under the previous system to start fresh under the new system. DIDD shall remove any limit on the number of times an employee may take the exam with no waiting period between attempts. After the second failure of the employee to pass the examination, the cost of further testing shall be shifted to the provider.

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.

~~November 4, 1998.~~

0465-01-03-.051200-20-12-.04 APPROVALS CERTIFICATION OF UNLICENSED PERSONNEL Certification of Unlicensed Personnel

- (1) ~~When a new unlicensed employee with prior medication administration training requests to administer medications in a program licensed by or under contract with the Division of Mental Retardation Services, t~~ The provider agency shall obtain confirmation proof of certification (participant record) for new employees from the Department of ~~an employee's approval status, including the date the employee was approved, before the new employee can they are allowed to administer medications.~~
- (2) The Department shall verify an employee's current status and date of last successful completion of the medication administration training program.
- (3) ~~When requested, a provider agency shall notify the Department in writing whenever an approved unlicensed employee has his or her approval to administer medication withdrawn by a provider agency.~~
- (4) ~~An unlicensed employee shall not be approved if such employee:-~~
 - (a) ~~is less than eighteen years of age;~~
 - (b) ~~has been convicted of a crime rationally related to his or her employment;~~
 - (c) ~~has not successfully completed an approved medication administration course;~~
 - (d) ~~received a grade below 80% for an approved medication administration course;~~
 - (e) ~~has not been approved by the provider agency to administer medications;~~
 - (f) ~~has failed to be re-tested every two years on medication administration in accordance with these rules;~~
 - (g) ~~has failed to retake the medication administration test when such individual has been previously approved to administer medications but has not worked with people with mental retardation/developmental disabilities for a period of six months; or~~
 - (h) ~~commits medication administration errors which demonstrate lack of competence.~~

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.
~~November 4, 1998.~~

0465-01-03-.061200-20-12-.05 LIMITATIONS ON FUNCTIONS OF UNLICENSED PERSONNELLimitations of Functions of Unlicensed Personnel

- (1) The following ~~procedures~~ may ~~not~~ be performed by ~~unlicensed~~certified personnel under the scope of these regulations and in accordance with the training curriculum:
 - (a) ~~endotracheal suctioning~~ Medication administration via the following routes; ~~oral, rectal, vaginal, eye, ear, nasal and topical; and~~
 - (b) ~~urinary catheter insertion~~ Administration of medications by subcutaneous route for routine insulin (with additional training) and injectable epinephrine (i.e. EpiPen).
 - (c) ~~nasogastric tube care;~~
 - (d) ~~intravenous therapy;~~
 - (e) ~~adjustment of doses of medications;~~
 - (f) ~~tracheotomy care;~~
 - (g) ~~administration of oxygen;~~
 - (h) ~~administration of fluxuating or mixing insulin dosages; and~~
 - (i) ~~administration of medications by subcutaneous, intramuscular, intradermal or intravenous route, except for routine insulin and one time life saving injections, such as EpiPens.~~
- (2) This regulation does not preclude the performance of procedures by ~~unlicensed~~certified 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.
~~November 4, 1998.~~

0465-01-03.071200-20-12-.06 PROVIDER AGENCY REQUIREMENTSProvider Agency Requirements

- (1) A provider agency ~~or program~~ employing ~~unlicensed~~certified personnel ~~must~~shall have a written policy ~~and procedure~~ demonstrating compliance with these rules ~~for any employees who administers medications. These~~ This policy ~~and procedures~~ ~~must~~shall be ~~approved~~ accepted by the Department prior to the implementation of medication administration by ~~unlicensed employees in that provider agency or program~~ and ~~must~~shall include, at a minimum, the following elements:
 - (a) Medication Prohibitions;
 - (b) Security;
 - (c) Program ~~r~~Requirements;
 - (d) Medication ~~s~~Storage and ~~l~~Labeling;

- (e) ~~Editing of Medication Records~~ medication Records;
 - (f) Medication ~~r~~Refusal;
 - (g) Medication Administration Record (MAR);
 - (h) Controlled ~~s~~Substances;
 - (i) Medication ~~v~~Variances;
 - (j) Medication ~~d~~Disposal;
 - (k) Family ~~v~~Visit; and
 - (l) Self-Administration.
- (2) A provider agency ~~must~~ shall have a separate Medication Administration Record (MAR) of ordered medications for each person ~~receiving medication~~. The record ~~documenting administration~~ 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, ~~ordering, or approving~~ practitioner;
 - (e) ~~s~~Starts date and stop dates, if applicable; and
 - (f) ~~expected therapeutic effects for the person taking the medication~~ Any specific directions;
 - (g) ~~possible side effects to the person taking the medication~~;
 - (h) ~~storage of medications~~; and
 - (i) ~~disposal of medications~~
- (3) ~~As a condition to authorizing or renewing the authorization to operate any provider agency or program that administers medications to persons with mental retardation/developmental disabilities, the Division shall require that the agency have employees qualified pursuant to these rules on duty at any time that the agency administers such medications. The agency must maintain a written record of each medication administered to each person. Such record will be subject to review by the Division as a part of its procedure in authorizing the continued operation of the provider agency and the provider agency's programs.~~ A provider agency ~~must~~ shall 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~~ shall be maintained in accordance with State and Federal laws and DIDD regulations.
- (5) The agency must have certified ~~staff~~ personnel available to administer medications as ordered and at a place convenient for the person.

~~0465-01-03-.081200-20-12-.07~~ **SUSPENSION TERMINATION OF AUTHORITY TO ADMINISTER-**
MEDICATION 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-personnel~~ 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 ~~services in the administration of~~ medications; or
 - (c) Failure to conform to the essential ~~standards~~ 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-certified personnel~~ by certified mail and he/she shall have the right to request an appeal hearing on his/her termination of authority to administer medications, pursuant to the Tennessee Uniform Administrative Procedures Act.

- ~~(2) Any such denial or suspension of the unlicensed employee's authority shall be reported to the Department in writing. 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, ~~4-5-301~~, 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.

~~November 4, 1998.~~

~~0465-01-03-.091200-20-12-.08~~ **MONITORING OF UNLICENSED PERSONNEL** Monitoring of Unlicensed Personnel

- (1) The Department ~~will~~ shall monitor the administration of medications by unlicensed ~~employees~~ personnel. ~~through quality enhancement surveys and follow-up m-~~ Monitoring ~~will~~ shall be completed by Registered Nurses employed by ~~or contracted with~~ the Department.
- (2) ~~Regarding medication administration, monitoring shall include, but not be limited to, review of each provider agency's evaluation and performance records for unlicensed employees who perform the functions and activities provided for in these rules. Such records shall encompass statements and observations by supervisors of unlicensed personnel made during the course of the work performed by the unlicensed employees. Monitoring may include direct observation of medication administration by unlicensed employees approved pursuant to these rules. The provider agency will~~ shall monitor, at a minimum, the first medication pass of the unlicensed personnel upon successful completion of their his/her 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.

~~November 4, 1998.~~

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

This rule should decrease by an estimated 31.6% the annual amount expended on medication administration training by small businesses who contract with the Department of Intellectual and Developmental Disabilities' and have employees that are required to complete medication administration training. This estimate is based on the total estimated annual savings of 31.6% for all the Department of Intellectual and Developmental Disabilities' service providers who have employees that are required to complete medication administration training.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

This rule should have no effect on local governments as the Department of Intellectual and Developmental Disabilities does not contract with local governments for the provision of services that require medication administration training.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The Department of Intellectual and Developmental Disabilities (DIDD) has an exemption from the Board of Nursing which allows training and certification of unlicensed personnel to administer medications after successful completion of a 20 hour Medication Administration curriculum. The training has been updated and approved by the Board of Nursing. To provide Regulatory Relief, DIDD proposes three significant changes: to extend the certification period from two years to three years, to increase the number of times someone can take the training to unlimited, but after 2 fails the cost for further testing would move to the agency, and to replace the present eight hour recertification training by on line material for review followed by a knowledge test and skills competency evaluation.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

DIDD is required by Title 68-1-904 to promulgate rules to provide competency-based training, education and appropriate monitoring of unlicensed personnel.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee citizens with Intellectual and/or Developmental Disabilities under a Medicaid Waiver operated by DIDD and those providers who contract with DIDD are directly affected. The Regulatory Relief Task Force, including the members who are providers, strongly supports these changes.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

NONE

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The result would be minimal since the estimated impact is less than \$50,000.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Dr. Thomas Cheetham, Deputy Commissioner, Health Services DIDD

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Lance Iverson, Debbie Payne, Tom Cheetham

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Dr. Thomas Cheetham, DIDD, 400 Deaderick Street, 10th Floor, Citizens Plaza, Nashville, TN 37243. 615-253-6711. Thomas.cheetham@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

The proposed changes will significantly reduce the cost to providers of training staff to safely administer medications to the people served by DIDD and maintain such competency.

Katelyn Smith

From: Kelly D. Young
Sent: Tuesday, January 12, 2016 10:36 AM
To: Katelyn Smith
Subject: DIDD Med Admin Rules

Katelyn,

Per our conversation, the attached authority below should be included with regard to the Purpose. Let me know if there is any other info you need.

“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.”



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