



Division of Developmental Disabilities
Bureau of Clinical Services

Section 2

Administrative Rule 116

State Published Copy of Administrative Rule 116

Annotated Copy of Administrative Rule 116

**Training Program
for
Authorized Non-licensed Direct Care Staff**

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS

The General Assembly's Illinois Administrative Code database includes only those rulemakings that have been permanently adopted. This menu will point out the Sections on which an emergency rule (valid for a maximum of 150 days, usually until replaced by a permanent rulemaking) exists. The emergency rulemaking is linked through the notation that follows the Section heading in the menu.

- [Section 116.10 Purpose](#)
- [Section 116.20 Definitions](#)
- [Section 116.30 Master Nurse-Trainer and Nurse-Trainers](#)
- [Section 116.40 Training and Authorization of Non-Licensed Staff by Nurse-Trainers](#)
- [Section 116.50 Administration of Medications](#)
- [Section 116.60 Medication Self-Administration](#)
- [Section 116.70 Medication Administration Record and Required Documentation](#)
- [Section 116.80 Storage and Disposal of Medications](#)
- [Section 116.90 Individual Health Supports and Assessment](#)
- [Section 116.100 Quality Assurance](#)
- [Section 116.110 Administrative Requirements](#)

AUTHORITY: Implementing and authorized by Section 15.4 of the Mental Health and Developmental Disabilities Administrative Act [20 ILCS 1705/15.4].

SOURCE: Emergency rule adopted at 23 Ill. Reg. 11988, effective September 13, 1999, for a maximum of 150 days; adopted at 24 Ill. Reg. 2656, effective February 7, 2000.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.10 PURPOSE

Section 116.10 Purpose

The purpose of this Part is to ensure the safety of individuals in programs funded by the Department of Human Services (DHS) by regulating the storage, distribution, and administration of medications in specific settings; training of non-licensed staff in the administration of medications. This applies exclusively to all programs for individuals with a developmental disability in settings of 16 persons or fewer that are funded or licensed by the Department of Human Services and that distribute or administer medications and all intermediate care facilities for the developmentally disabled with 16 beds or fewer that are licensed by the Illinois Department of Public Health.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.20 DEFINITIONS

Section 116.20 Definitions

The words and phrases used in this Part shall mean the following, except where a different meaning is clearly intended from the context:

"Administer" or "Administration." An act in which a single dose of medication is instilled into the body of, applied to the body of, or otherwise given to a person for immediate consumption or use, exclusive of injection or other similar methods of transmission.

"Adverse drug reaction." A person's response to medication that has an undesirable effect and may be harmful to the health of a person. The reaction may be temporary and resolve itself without lasting effects or it may require interventions to be resolved.

"Agency." Any organization that operates a residential program for persons with developmental disabilities.

"Authorized direct care staff." Non-licensed persons who have successfully completed a medication administration training program specified by the Illinois Department of Human Services (DHS) and conducted by a nurse-trainer. This authorization is specific to an individual receiving services in a specific agency and does not transfer to another agency [20 ILCS 1705/15.4(b)] or individual.

"Community residence." Any residence funded by DHS and provided by a licensed agency, or a residential setting certified or approved by DHS, or an intermediate care facility for 16 or fewer persons with developmental disabilities, licensed by the Illinois Department of Public Health (DPH) as an Intermediate Care Facility for the Developmentally Disabled (ICF/DD-16), 16 beds or fewer.

"Competency-based." Training which is tied to an identified set of skills and knowledge and requires documentation of an acceptable level of performance of a task or achievement of an outcome.

"Controlled substance." Any drug or other substance listed pursuant to a schedule in the Illinois Controlled Substances Act [720 ILCS 570].

"Days." Unless otherwise indicated, all references to days within the text of this

Part refers to working days.

"DD Clinical Director." The physician serving as the clinical director of the Office of Developmental Disabilities, Division of Disability and Behavioral Health Services, Illinois Department of Human Services, or designee.

"Delegation." The transfer of responsibility for the performance of selected tasks by the registered nurse (RN) to qualified, competent assistive personnel in a selected situation, based upon the RN's plan of care. The RN retains professional accountability for the outcome of the delegated task and all the nursing care of the individual. No redelegation by assistive personnel may occur.

"Department." The Illinois Department of Human Services (DHS).

"Distribute or distribution." The act of controlling access to medications and allowing access by individuals to their medications at prescribed times.

"DPA." The Illinois Department of Public Aid.

"DPH." The Illinois Department of Public Health.

"Functional literacy." An individual's ability to read, write, speak, compute and solve problems at levels of proficiency necessary to function on the job as assessed by standardized techniques.

"Guardian." The parent of a child under the age of 18 whose parental rights have not been terminated or a person appointed by a court to be guardian of the individual.

"Individual." Any person with a developmental disability receiving services from a program.

"Intermediate care facility for the developmentally disabled (ICF/DD-16)." A residence licensed by the Illinois Department of Public Health to provide health or habilitative care on a long-term basis for 16 or fewer individuals with developmental disabilities.

"Licensed person or personnel." A physician, a registered professional nurse, an advanced practice nurse, a licensed practical nurse, a dentist, a pharmacist, a physician assistant, or a podiatrist licensed in the State of Illinois.

"Master nurse-trainer." An employee of DHS who is a registered professional nurse who has been designated by the DD Clinical Director to train/educate nurse-trainers.

"Medication." A drug prescribed for the individual by a physician, a physician assistant, an advanced practice nurse, a dentist, a podiatrist, or a certified optometrist, including drugs to be taken on a PRN basis and over-the-counter drugs.

"Medication error." The administration of medication other than as prescribed resulting in the wrong medication being taken, or medication being taken at the wrong time, or in the wrong dosage, or via the wrong route, or by the wrong person,

or omitted entirely. It is meant to include a lack of documentation of medication administration or any error in that documentation. Medication errors must be reported to the DHS Bureau of Quality Enhancement or to the Illinois Department of Public Health Regional Office (if the individual is a resident of an ICF/DD-16) in accordance with written instructions from the Department's Bureau of Quality Enhancement or DPH rules (77 Ill. Adm. Code 350). All medication errors are subject to review by DHS or DPH, whichever is applicable. Medication errors that meet the reporting criteria pursuant to the Department's rules on Office of Inspector General Investigations of Alleged Abuse or Neglect or Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50) shall be reported to the Office of Inspector General.

"Medication administration record." A written record of medications prescribed for, and administered to, an individual.

"Non-licensed staff training program." *A standardized competency-based medication administration training program approved by the Illinois Department of Human Services. It is conducted by a nurse-trainer for the purpose of training persons employed or under contract to provide direct care or treatment to individuals receiving services to administer medications and implement self-administration of medication training to individuals under the supervision and monitoring of the nurse-trainer. It incorporates adult learning styles, teaching strategies, classroom management, curriculum overview including ethical-legal aspects, and standardized competency-based evaluations on administration of medications and self-administration of medication training programs.* [20 ILCS 1705/15.4(b)]

"Normalization." A philosophy under which persons with a developmental disability are provided or restored to patterns and conditions of everyday life which are as close as possible to norms and patterns of the mainstream of society.

"Nurse-trainer." A registered professional nurse and/or advanced practice nurse who has successfully completed the DHS nurse-trainer training program.

"Nurse-Trainer Training Program." *A standardized competency-based medication administration program provided by the Illinois Department of Human Services and conducted by a DHS master nurse-trainer. Nurse-trainers shall train persons employed or under contract to provide self-administration of medication training to individuals under the supervision and monitoring of the nurse-trainer. It incorporates adult learning styles, teaching strategies, classroom management and a curriculum overview including the ethical and legal aspects of supervising those administering medication.* [20 ILCS 1705/15.4(b)]

"Patent or proprietary medications." Medications and household remedies that are generally considered and accepted as harmless and nonpoisonous when used according to the directions on the label and for which there are written physician orders for their use.

"Physician." A physician licensed to practice medicine in all of its branches.

"PRN." Prescribed medications, to be taken as needed, for specific conditions.

"Registered professional nurse." A person licensed as a professional nurse as defined in the Illinois Nursing and Advanced Practice Nursing Act [225 ILCS 65].

"Self-administration." An act in which an individual administers his or her own medications. To be considered "capable of self-administering medications", individual residents must, at a minimum, be able to identify prescribed medication by size, shape, or color and know when it should be taken and in what amount it should be taken each time. [20 ILCS 1705/15.4(b)]

"Substantial compliance." Meeting the requirements set forth in this Part, except for variations from the strict and literal performance of such requirements that result in insignificant omissions and defects, given the particular circumstances and the history of those omissions and defects. Omissions that have an adverse impact on an individual's health and safety shall be considered significant and shall be considered substantial noncompliance.

"Supervision." An active process in which the Registered Professional Nurse monitors, directs, guides, and evaluates the outcomes of an activity or task. The registered nurse maintains the accountability for the tasks and responsibilities, as subcomponents of total patient care, delegated to qualified competent assistive personnel.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.30 MASTER NURSE-TRAINER AND NURSE-TRAINERS

Section 116.30 Master Nurse-Trainer and Nurse-Trainers

- a) The Department's master nurse-trainers are designated by the DD Clinical Director and shall meet the following criteria:
 - 1) Demonstration of competence to teach adult learners through:
 - A) evidence of previous teaching or training experience; or
 - B) completion of courses in teaching and instructing.
 - 2) Possession of two years of clinical registered professional nursing experience within the last five years, at least one of which shall have been in developmental disabilities.
- b) All registered professional nurses seeking approval to be nurse-trainers to provide medication administration training to non-licensed staff shall:
 - 1) Be licensed as a registered professional nurse or advanced practice nurse in Illinois.
 - 2) Possess two years of clinical registered professional nursing experience within the last five years, at least one of which shall preferably have been in developmental disabilities.
 - 3) Have successfully completed the DHS Nurse-Trainer Training Program.
- c) Requests for approval as a Nurse-Trainer shall be submitted, in writing, to the DD Clinical Director. The DD Clinical Director shall approve all requests that show substantial compliance with the requirements. The decision to approve or deny requests shall be on file with the Department, which shall maintain a list of all approved Nurse-Trainers.
- d) The DD Clinical Director shall, upon request, grant conditional approval to a registered professional nurse who fulfills the requirements but has not completed the required nurse-trainer course of instruction. Conditional approval shall be granted for no more than 90 days following the date of conditional approval. The nurse given conditional approval shall not train or authorize non-licensed staff to administer medications, but may direct and monitor, as well as educate and train, previously authorized direct care staff on new medications or dosage changes as shall be required.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.40 TRAINING AND AUTHORIZATION OF NON-LICENSED STAFF BY
NURSE-TRAINERS

Section 116.40 Training and Authorization of Non-Licensed Staff by Nurse-Trainers

- a) Only a nurse-trainer may delegate and supervise the task of medication administration to direct care staff.
- b) *Prior to training non-licensed staff to administer medication, each nurse-trainer shall perform the following for each individual to whom medications will be administered by non-licensed staff [20 ILCS 1705/15.4(c)] once they are trained and authorized direct care staff:*
 - 1) An assessment of the individual's physical and mental status and medical history.
 - 2) An evaluation of the medication orders and medications prescribed.
- c) Non-licensed direct care staff who are to be authorized to administer medications under the delegation of the registered professional nurse shall meet the following criteria:
 - 1) be age 18 or older;
 - 2) complete high school or its equivalency (G.E.D.);
 - 3) demonstrate functional literacy;
 - 4) satisfactorily complete the Health and Safety component of the Direct Support Persons Core Training Program or a DHS approved equivalent Developmental Disabilities Aide Training Program;
 - 5) be initially trained and evaluated by a nurse-trainer in a competency-based, standardized medication curriculum specified by DHS;
 - 6) receive specific additional competency-based training and assessment by a nurse-trainer as deemed necessary by the nurse-trainer whenever a change of medication or dosage occurs or a new individual that requires medication enters the program;

- 7) pass the written portion of the comprehensive examination furnished by DHS based on the information conveyed to them; and
 - 8) score 100% on a written or oral competency-based evaluation specifically pertinent to those medications that such staff are responsible to administer.
- d) Initial competency-based training toward delegation for medication administration shall include:
- 1) Best practice standards related to the rights of individuals, legal and ethical responsibilities, agency procedures and communication pertaining to medication administration.
 - 2) Best practice nursing techniques associated with medication administration.
 - 3) Classes of drugs and their effects and common side-effects.
 - 4) Specific information regarding the individuals to whom the staff will administer medication and the medication the staff will administer.
 - 5) Techniques to check, evaluate, report and record vital signs when those skills are necessary for the safe administration of medication to that individual.
 - 6) A final, individual-specific, competency-based evaluation performed by a nurse-trainer for each medication administered to persons at the program for whom the staff provide supports.
- e) *Authorized direct care staff shall be re-evaluated by a nurse-trainer at least annually or more frequently at the discretion of the registered professional nurse. Any retraining shall be to the extent that is necessary to ensure competency of the authorized direct care staff to administer medication [20 ILCS 1705/15.4(c)], as judged by a nurse-trainer.*
- f) *Direct care staff who fail to qualify for competency to administer medications shall be given additional education and testing to meet criteria for delegation authority to administer medications. Any direct care staff person who fails to qualify as an authorized direct care staff after initial training and testing must, within three months, be given another opportunity for retraining and retesting. A direct care staff person who fails to meet criteria for delegated authority to administer medication, including, but not limited to, failure of the written test on two occasions, shall be given consideration for shift transfer or reassignment, if possible. No employee shall be terminated for failure to qualify during the three month time period following initial testing. Refusal to complete training and testing required by this Section may be grounds for immediate dismissal. [20 ILCS 1705/15.4(h)]*
- g) *No authorized direct care staff person delegated to administer medication shall be subject to suspension or discharge for errors resulting from the staff person's acts or omissions when performing the functions unless the staff person's actions or omissions constitute willful and wanton conduct [20 ILCS 1705/15.4(i)].*
- h) *Authorization of staff to administer medication shall be revoked if, in the opinion of*

the registered professional nurse-trainer, the authorized direct care staff person is no longer competent to administer medication [20 ILCS 1705/15.4(c)]. The degree of retraining and reassessment of competency should occur at the discretion of the nurse-trainer.

- i) Clear documentation of training, retraining, and evaluation shall be kept in each staff or contractual person's personnel file by each agency where authorized direct care staff are employed.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.50 ADMINISTRATION OF MEDICATIONS

Section 116.50 Administration of Medications

- a) Medications shall be administered in accordance with the Mental Health and Developmental Disabilities Administrative Act [20 ILCS 1705] and the Illinois Nursing and Advanced Practice Nursing Act [225 ILCS 65].
- b) Non-licensed staff shall not administer any medication in an injectable form.
- c) *A registered professional nurse, advanced practice nurse, physician licensed to practice medicine in all of its branches, or physician assistant shall be on duty or on call at all times in any program covered by this Part [20 ILCS 1705/15.4(j)].*
- d) Authorized direct care staff shall not administer PRN medications unless there is a written protocol approved by a nurse-trainer and prescribing practitioner for each individual and for each medication. A written protocol shall include the following information:
 - 1) the name of the individual;
 - 2) the name, route, and dosage form of the medication;
 - 3) dosage or quantity to be taken;
 - 4) frequency or times of administration;
 - 5) conditions for which the medication may be given;
 - 6) contraindications for the medications;
 - 7) a maximum or stop dosage;
 - 8) any necessary special directions and precautions for the medication's preparation and administration;
 - 9) common severe side or adverse effects or interactions and the action required if they occur; and
 - 10) proper storage.

- e) A facility may stock for use as PRN medications, and in accordance with subsection (d) above, only drugs that are regularly available without prescription at a commercial pharmacy, such as: uncontrolled cough syrups, laxatives, and analgesics. These shall be given to an individual only upon the written order of the physician, dentist, or podiatrist; shall be administered from the original containers; and shall be recorded in the individual's medication administration record (MAR).

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.60 MEDICATION SELF-ADMINISTRATION

Section 116.60 Medication Self-Administration

- a) *As part of the normalization process, in order for each individual to attain the highest possible level of independent functioning, all individuals shall be permitted to participate in their total health care program [20 ILCS 1705/15.4(d)]. Every program shall include, but not be limited to, individual training in promoting wellness, prevention of disease and medication self-administration procedures.*
- 1) *Every program shall adopt written policies and procedures for assisting individuals in obtaining preventative health and medication self-administration skills in consultation with the registered professional nurse [20 ILCS 1705/15.4(d)].*
 - 2) Individuals shall be evaluated to determine their self-administration of medication capabilities by a nurse-trainer through the use of DHS required, standardized screening and assessment instruments.
 - 3) *When the results of the screening and assessment indicate an individual not to be independently capable to self-administer his or her own medications, programs shall be developed in consultation with the Community Support Team (CST) or Interdisciplinary Team (IDT) to provide individuals with [20 ILCS 1705/15.4(d)] medication self-administration training as identified in each individual's treatment/service plan.*
- b) Each individual shall be presumed to be competent to self-administer medications if he or she has been determined to be:
- 1) capable by a registered professional nurse or advanced practice nurse;
 - 2) approved to self-administer medication by the individual's Community Support Team (CST) or Interdisciplinary Team (IDT); and
 - 3) authorized by a written order of a physician licensed to practice medicine in all of its branches.
- c) Training of individuals to self-administer medication shall minimally include instruction, for each medication prescribed, in the following areas:

- 1) name of medication or identification within the existing agency pharmacy protocol;
 - 2) dosage or quantity to be taken;
 - 3) route of administration;
 - 4) frequency or times of administration;
 - 5) purpose of medication, special instructions, common side-effects and potential consequences of not taking the medication or of not taking the medication properly; and
 - 6) when to seek medical assistance and any action to be taken in the event of a missed dose, medication error, or adverse drug reaction.
- d) When requested to do so by an individual, authorized direct care staff may assist an individual in the self-administration of medications by taking the medication from the locked area where it is stored and handing it to the individual. If the individual is physically unable to open the container, a staff member may open the container for the individual. Agency staff may also assist physically impaired individuals, such as those who have arthritis, cerebral palsy, or Parkinson's disease, in the removal of the medication from the container and in consuming or applying the medication.
- e) Each individual shall remain under observation by authorized direct care staff and be assisted by the staff to correct or prevent medication errors and to safeguard against adverse drug reactions. All observation and assistance shall be noted in the progress section of the individual's clinical record.
- f) Individuals specifically determined to be competent, by a physician who has issued a written order, to self-administer their own medications may maintain possession of the key or combination of the lock to their own medication storage area. A duplicate key or a copy of the combination shall be kept by the program in a secure location for emergency use, such as if the individual should lose or misplace the key or forget the combination.
- g) A medication administration record need not be kept for those individuals for whom the attending physician has given permission to have access to their own medications and to be fully responsible for taking their own medications.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.70 MEDICATION ADMINISTRATION RECORD AND REQUIRED DOCUMENTATION

Section 116.70 Medication Administration Record and Required Documentation

- a) All medications, including patent or proprietary medications (e.g., cathartics, headache remedies, or vitamins, but not limited to those) shall be given only upon the written order of a physician, advanced practice nurse, or physician assistant. Rubber stamp signatures are not acceptable. All orders shall be given as prescribed by the physician and at the designated time. Telephone orders may be taken by a registered professional nurse or licensed practical nurse. All orders shall be immediately written on the individual's clinical record or a "telephone order form" and signed by the nurse taking the order. These orders shall be countersigned or documented by facsimile prescription by the physician within ten working days.
- b) Medication Administration Record
 - 1) An individual medication administration record shall be kept for each individual for medications administered and shall contain at least the following:
 - A) the individual's name;
 - B) the name and dosage form of the drug;
 - C) the name of the prescribing physician, physician assistant, dentist, podiatrist, or certified optometrist;
 - D) dose;
 - E) frequency or times of administration;
 - F) route of administration;
 - G) date and time given;
 - H) most recent date of the order;
 - I) allergies to medication; and

- J) special considerations.
- 2) The medication administration record for the current month shall be kept with the medications or in the individual's clinical record. If logs are kept in the individual's clinical record, the record shall be present when and where the medications are taken so that the appropriate notation can be made in the log.
 - 3) The medication administration record shall be completed and initialed immediately after the medication is administered by the authorized direct care staff. Each medication administration record shall have a section that contains the full signature and title of each individual who initials the medication administration record.
 - 4) All changes in medication shall be noted on the medication administration record by a licensed practical nurse, registered professional nurse, advanced practice nurse, pharmacist, physician, physician assistant, dentist, podiatrist, or certified optometrist and reported to the registered professional nurse in charge of the program prior to the next dose.
 - 5) Individual refusal to take medications shall be noted in the medication administration record. A progress note by authorized direct care staff shall be written in the individual's clinical record indicating the reasons for refusal and the registered professional nurse shall be notified.
 - 6) For individuals who are independently self-administering medications, no medication administration record shall be required. However, any medication that individuals take shall be listed in their clinical records, including dosage, frequency, and identity of the prescribing physician, physician assistant, dentist, podiatrist, or certified optometrist. Each agency shall develop and implement a quality assurance system to ensure that self-administered medications are taken in accordance with prescribed orders.
- c) In the event of a medication error, authorized direct care staff shall immediately report the error to the registered professional nurse, advanced practice nurse, physician, physician assistant, dentist, podiatrist, or certified optometrist to receive direction on any action to be taken. All medication errors shall be documented in the individual's clinical record and a medication error report shall be completed within eight hours or before the end of the shift in which the error was discovered, whichever is earlier. The medication error report shall be sent to the nurse-trainer for review and further action. A copy of the medication error report shall be maintained as part of the agency's quality assurance program. Medication errors must be reported to the DHS Bureau of Quality Enhancement (or the Illinois Department of Public Health Regional Office if an individual of an ICF/DD-16 is involved) in accordance with written instructions from the Department's Bureau of Quality Enhancement or DPH rules (77 Ill. Adm. Code 350). All medication errors are subject to review by DHS or DPH, whichever is applicable. Medication errors that meet the reporting criteria pursuant to the Department's rules on Office of Inspector General Investigations of Alleged Abuse or Neglect or Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50) shall be reported to the Office of Inspector General.

- d) In the event of suspected drug reaction, authorized direct care staff shall immediately report the signs and symptoms to the registered professional nurse, advanced practice nurse, physician, physician assistant, dentist, podiatrist, or certified optometrist to receive direction on any action to be taken. All adverse drug reactions shall be documented in the individual's clinical record and an adverse drug reaction report shall be completed within eight hours or before the end of the shift in which the reaction was discovered, whichever is earlier. The adverse drug reaction report shall be sent to the prescriber and the nurse-trainer for review and further action. A copy of the adverse drug reaction report shall be maintained as a part of the agency's quality assurance program.
- e) An inventory and a record of use of controlled substances shall be maintained by the registered professional nurse in the program, and each substance shall require a separate sheet indicating the:
- 1) name of the individual;
 - 2) name of the prescriber;
 - 3) serial number of the prescription;
 - 4) name of the drug and strength;
 - 5) amount used;
 - 6) amount remaining;
 - 7) time and date administered;
 - 8) name of the individual who administered the medication; and
 - 9) documentation of a shift count done by authorized direct care staff. Any discrepancies shall be reported to the nurse-trainer for review and action in accordance with written policy.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.80 STORAGE AND DISPOSAL OF MEDICATIONS

Section 116.80 Storage and Disposal of Medications

- a) All drugs shall be stored in locked compartments or within the locked medicine container, cabinet or closet.
- b) Access to medications shall be limited to licensed and authorized direct care staff. Each program shall maintain an up-to-date list of authorized direct care staff on its premises.
- c) Each program shall have a written procedure for safeguarding medications kept in an individual's room or possession and shall require medications to be stored when individual safety cannot otherwise be assured.
- d) All medications shall be stored in their original containers.
- e) All prescription medications that are given to individuals at the direction of the physician, registered professional nurse, advanced practice nurse, pharmacist, physician assistant, dentist, podiatrist, or certified optometrist shall have a label with the same information as would appear on a pharmacy label in accordance with Section 22 of the Illinois Pharmacy Practice Act [225 ILCS 85] to show:
 - 1) the name and address of the pharmacy where the prescription is sold or dispensed;
 - 2) the name or initials of the person authorized to practice pharmacy;
 - 3) the date on which the prescription was filled;
 - 4) the name of the patient;
 - 5) the serial number of the prescription as filed in the prescription files;
 - 6) the last name of the practitioner who prescribed the prescription;
 - 7) the directions for use as contained in the prescription; and
 - 8) the proprietary name or names or the established name of the drugs, the dosage, and the quantity.
- f) Disposal of all medications shall be in accordance with federal and State laws.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.90 INDIVIDUAL HEALTH SUPPORTS AND ASSESSMENT

Section 116.90 Individual Health Supports and Assessment

- a) The registered professional nurse shall assess an individual's health status at least annually or more frequently at the discretion of the registered professional nurse.
- b) A physician shall assess an individual's health status at least annually or more frequently at the discretion of the physician or at the request of the agency or the registered professional nurse.

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.100 QUALITY ASSURANCE

Section 116.100 Quality Assurance

- a) A registered professional nurse, advanced practice nurse, licensed practical nurse, pharmacist or physician shall review the following for all individuals:
 - 1) medication orders;
 - 2) medication labels and medications listed on the medication administration record to ensure that they match physician orders; and
 - 3) medication administration records (for persons who are not self-medicating) to ensure that they are completed appropriately for:
 - A) medication administered as prescribed;
 - B) refusal by the individual; and
 - C) full signatures provided for all initials used.
- b) Reviews shall occur at least quarterly, but may be done more frequently at the discretion of the registered professional nurse and/or advanced practice nurse.
- c) A quality assurance review of medication errors for the purpose of monitoring and recommending corrective action shall be conducted within seven days after occurrence and included in the annual review.
- d) Documentation of the review and the review date shall be retained for at least five years.
- e) All quality assurance records shall be confidential and may only be disclosed in accordance with the provisions of Part 21 of Article VIII of the Code of Civil Procedure [735 ILCS 5/8-2101 through 8-2105].
- f) Nothing in this Part shall limit or restrict the reporting of medication errors as possible abuse or neglect or the investigation by the Office of Inspector General of possible abuse or neglect in accordance with the Department's rules on Office of Inspector General Investigations of Alleged Abuse or Neglect and Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50).

Joint Committee on Administrative Rules
ADMINISTRATIVE CODE

TITLE 59: MENTAL HEALTH
CHAPTER I: DEPARTMENT OF HUMAN SERVICES
PART 116 ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS
SECTION 116.110 ADMINISTRATIVE REQUIREMENTS

Section 116.110 Administrative Requirements

- a) Written policies and procedures shall be developed by each agency that include:
 - 1) Provisions for on-going supervision and monitoring of authorized direct care staff.
 - 2) Provisions for annual review and any necessary retraining of authorized direct care staff in theory and practice of medication administration.
 - 3) Provisions for a systematic review of all medication errors, adverse drug reactions, and incidents to identify contributing factors and plan corrective action.
 - 4) Provisions for recording and reporting of all instances of retraining and retesting for failure to qualify as an authorized direct care staff.
- b) Each program shall have written policies and procedures to include the governing of:
 - 1) distribution of medications, including controlled substances, and persons authorized to distribute medications;
 - 2) administration of medications;
 - 3) quality assurance medication review;
 - 4) storage and safekeeping of medications;
 - 5) disposal of medications, including controlled substances; and
 - 6) training, review and any necessary retraining of authorized direct care staff.
- c) Policies and procedures shall be consistent with applicable rules, regulations, and federal and State law.
- d) Each program shall have a copy of all policies and procedures related to medication on file and readily available to all programs at all times.

ADMINISTRATIVE RULE 116 – ADMINISTRATION OF MEDICATION IN COMMUNITY SETTINGS – Annotated.

Disclaimer – This document is a correlation of Administrative Rule 116 – Administration of Medication in Community Settings (hereafter referred to as the Rule) with the published results of Question and Answer (Q/A) sessions (Forums) completed after the Rule came into effect. These were published by the Illinois Department of Human Services, Office of Developmental Disabilities (now the Division of Developmental Disabilities) Bureau of Human resources Development newsletter – Developments. It is NOT an official copy of the Rule. Some Q/A are referred to rather than included, not included or abbreviated due to their length or duplication by other Q/A. Some Q/A speak to more than one part of the Rule. This is not necessarily indicated. Additionally, Memos and other already published state documents are referred to.

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Table of Contents by Section

116.10	Purpose
116.20	Definitions
116.30	Master Nurse-Trainer and Nurse-Trainers
116.40	Training and Authorization of Non-Licensed Staff by Nurse-Trainers
116.50	Administration of Medications
116.60	Medication Self-Administration
116.70	Medication Administration Record and Required Documentation
116.80	Storage and Disposal of Medications
116.90	Individual Health Supports and Assessment
116.100	Quality Assurance
116.110	Administrative Requirements

Questions, in *italic*, and answers, in un-modified type, are in the left column correlated with the appropriate section of the Rule in the right column. The Rule is a copy of Administrative Rule 116 - Administration of Medication in Community Settings.

See Appendix Q/A # 1 through 3.

[.10] *What is the correlation between Rule 116 and Rule 115?* They are two different rules. There is nothing in the Medication Administration Rule 116 that conflicts with the CILA Rule 115. Rule 116 supports self-medication programs and achieving optimal independence, but in a safe manner. The CILA Rule 115 covers other aspects of the program.

[.10] *Do agencies have to participate in this program?* Agencies (residential DD with 16 or fewer beds) have the choice of using licensed nurses or authorized DSP's under an RN Nurse-Trainer's supervision to administer medication to those individuals who are not independent in self-administration of their own medications.

[.10] *What if we can't get parents/family/guardians to comply with medication procedures?* Parents/family/guardians must be instructed in the process of medication administration for use during home visits. What they choose to do with the information is up to them. I suggest that your agency do its best to have them comply. You should document any lack of compliance and seek liability consultation as you see fit. Use your pharmacy and nurse to assist as much as possible.

See Appendix Q/A # 4 through 5

See Appendix Q/A # 6 through 8

[.20] *"Authorized direct care staff." Why can't the staff be called med techs or be certified?* RN delegation and supervision are key concepts underlying the intent of the role of non-licensed staff in the medication administration program in Illinois.

Section 116.10 Purpose

The purpose of this Part is to ensure the safety of individuals in programs funded by the Department of Human Services (DHS) by regulating the storage, distribution, and administration of medications in specific settings, training of non-licensed staff in the administration of medications. This applies exclusively to all programs for individuals with a developmental disability in settings of 16 persons or fewer that are funded or licensed by the Department of Human Services and that distribute or administer medications and all intermediate care facilities for the developmentally disabled with 16 beds or fewer that are licensed by the Illinois Department of Public Health.

Section 116.20 Definitions

The words and phrases used in this Part shall mean the following, except where a different meaning is clearly intended from the context:

"Administer" or "Administration" An act whereby a single dose of medication is instilled into the body of, applied to the body of, or otherwise given to a person for immediate consumption or use, exclusive of injection or other similar methods of transmission.

"Adverse drug reaction." A person's response to medication which has an undesirable effect and may be harmful to the health of a person. The reaction may be temporary and resolve itself without lasting effects or it may require interventions to be resolved.

"Agency." Any organization which operates a residential program for persons with developmental disabilities.

"Authorized direct care staff." Non-licensed person who have successfully completed a medication administration training program specified by the Illinois Department of Human Services (DHS) and conducted by a nurse-trainer. This authorization is specific to an individual receiving services in a specific agency and does not transfer to another agency [20 ILCS 1705/15.4 (b)] or individual.

Certification or med techs imply a different type of program, one of a more independently functioning non-licensed practitioner.

[.20] "Authorized direct care staff." *Can direct care staff be cross-trained in more than one house? Yes.*

[.20] "Authorized direct care staff." *Can authorized direct care staff go to DT to administer medications for individuals they have been trained to do? No.* DT/workshop settings must have a nurse administer medications at these sites or the individual must be independent in self-administration.

[.20] "Authorized direct care staff." *Do all staff have to be authorized if they work in the house? All staff who have anything to do with medications must be authorized.*

See Appendix Q/A # 9 and 10

[.20] "Delegation." means the transferring to an individual the authority to perform a selected nursing activity or task, in a selected situation. [Illinois Nurse Practice Act, 1225 ILCS 65/50-75; Section 50-75 (a)]

[.20] "Delegation." *Just exactly what am I delegating to authorized direct care staff?* You are delegating the physical act of medication administration tasks. Nowhere in this act (rule) are you allowed to delegate judgment or assessment.

"Community residence." Any residence funded by DHS and provided by a licensed agency, or a residential setting certified or approved by DHS, or an intermediate care facility for 16 or fewer persons with developmental disabilities, licensed by the Illinois Department of Public Health (DPH) as an Intermediate Care Facility for the Developmentally Disabled (ICF/DD-16), 16 beds or fewer.

"Competency-based." Training which is tied to an identified set of skills and knowledge and requires documentation of an acceptable level of performance of a task or achievement of an outcome.

"Controlled substance." Any drug or other substance listed pursuant to a schedule in the Illinois Controlled Substances Act [720 ILCS 570].

"Days." Unless otherwise indicated, all references to days within the text of this Part refers to working days.

"DD Clinical Director." The physician serving as the clinical director of the Office of Developmental Disabilities, Division of Disability and Behavioral Health Services, Illinois Department of Human Services, or designee.

"Delegation." The transfer of responsibility for the performance of selected tasks by the registered nurse (RN) to qualified, competent assistive personnel in a selected situation, based upon the RN's plan of care. The RN retains professional accountability for the outcome of the delegated task and all the nursing care of the individual. No re-delegation by assistive personnel may occur.

"Department." The Illinois Department of Human Services (DHS).

"Distribute or distribution." The act of controlling access to medication(s) and allowing access by individuals to their medication(s) at prescribed times.

"DPA." The Illinois Department of Public Aid.

"DPH." The Illinois Department of Public Health.

"Functional literacy." An individual's ability to read, write, speak, compute and solve problems at levels of proficiency necessary to function on the job, as assessed by standardized techniques.

"Guardian." The parent of a child under the age of 18 whose parental rights have not been terminated or a person appointed by a court to be guardian of the individual.

"Individual." Any person with a developmental disability receiving services from a program.

"Intermediate care facility for the developmentally disabled (ICF/DD-16)." A residence licensed by the Illinois Department of Public Health to provide health or habilitative care on a long-term basis for 16 or fewer individuals with developmental disabilities.

"Licensed person or personnel." A physician, a registered professional nurse, an advanced practice nurse, a licensed practical nurse, a dentist, a pharmacist, a physician assistant, or a podiatrist licensed in the State of Illinois.

"Master nurse-trainer." An employee of DHS who is a registered professional nurse who has been designated by the DD Clinical Director to train/education nurse-trainers.

"Medication." A drug prescribed for the individual by a physician, a physician assistant, an advanced practice nurse, a dentist, a podiatrist, or a certified optometrist, including drugs to be taken on a PRN basis and over-the-counter drugs.

"Medication error." The administration of medication other than as prescribed resulting in the wrong medication being taken, or medication being taken at the wrong time, or in the wrong dosage, or via the wrong route, or by the wrong person, or omitted entirely. It is meant to include a lack of documentation of medication administration or any error in that documentation. Medication errors must be reported to the DHS Bureau of Quality Enhancement or to the Illinois Department of Public Health Regional Office (if the individual is a resident of an ICF/DD-116) in accordance with written instructions from the Department's Bureau of Quality Enhancement or DPHs rules (77 Ill. Adm. Code 350). All medications errors are subject to review by DHS or DPH, whichever is applicable. Medication errors which meet the reporting criteria pursuant to the Department's rule on Office of Inspector General Investigations of Alleged Abuse or Neglect or Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50) shall be reported to the Office of Inspector General.

"Medication administration record." A written record of medications prescribed for, and administered to, an individual.

"Non-licensed staff training program." A standardized competency-based medication administration training program approved by the Illinois Department of Human Services. It is conducted by a nurse-trainer for the purpose of training persons employed or under contract to provide direct care or treatment to individuals receiving services to administer medications and implement self-administration of medication training to individuals under the supervision and monitoring of the nurse-trainer. It incorporates adult learning styles, teaching strategies, classroom management, curriculum overview including ethical-legal aspects, and standardized competency-based evaluations on administration of medications and self-administration of medication training programs. [20 ILCS 1705/15.4 (b)]

“Normalization.” A philosophy under which persons with a developmental disability are provided or restored to patterns and conditions of everyday life which are as close as possible to norms and patterns of the mainstream of society.

“Nurse-Trainer.” A registered professional nurse and/or advanced practice nurse who has successfully completed the DHS nurse-trainer training program.

“Nurse-Trainer Training Program.” A standardized competency-base medication administration program provided by the Illinois Department of Human Services and conducted by a DHS master nurse-trainer. Nurse-trainers shall train persons employed or under contract to provide self-administration of medication training to individuals under the supervision and monitoring of the nurse-trainer. It incorporates adult learning styles, teaching strategies, classroom management and a curriculum overview including the ethical and legal aspects of supervising those administering medication. [20 ILCS 1705/15.4 (b)]

“Patient or proprietary medications.” Medications and household remedies which are generally considered and accepted as harmless and nonpoisonous when used according to the directions on the label and for which there are written physician orders for their use.

“Physician.” A physician licensed to practice medicine in all of its branches.

“PRN.” Prescribed medications, to be taken as needed, for specific conditions.

“Registered professional nurse.” A person licensed as a professional nurse as defined in the Illinois Nursing and Advanced Practice Nursing Act. [225 ILCS 65].

“Self-administration.” An act whereby an individual administers his or her own medications. To be considered “capable of self-administering medications,” individual residents must, at a minimum, be able to identify prescribed medication by size, shape, or color and know when it should be taken and in what amount it should be taken each time. [20 ILCS 1705/15.4 (b)]

“Supervision.” An active process in which the Registered Professional Nurse monitors, directs, guides, and evaluates the outcomes of an activity or task. The registered nurse maintains the accountability for the tasks and responsibilities, as subcomponents of total patient care, delegated to qualified competent assistive personnel.

Section 116.30 Master Nurse-Trainer and Nurse-Trainers

- a) The Department’s master nurse-trainer(s) are designated by the DD Clinical Director and shall meet the following criteria:
 - 1) Demonstration of competence to teach adult learners through:
 - A) evidence of previous teaching or training experience; or
 - B) completion of courses in teaching and instructing.
 - 2) Possession of two years of clinical registered professional nursing experience within the last five years, at least one of which shall have been in developmental disabilities.
- b) All registered professional nurses seeking approval to be nurse-trainers to provide medication administration training to non-licensed staff shall preferably have been in developmental disabilities.

See Appendix Q/A # 11 through 13

[.30 (b) 1)] *Are the nurse trainer classes a one-time attendance, or is updated information given?* The Medication Administration training is a one-time event...(the rest of the answer no longer applies.)

[.30 (b) 1)] *Can a LPN with years of experience do the training, with a RN signing off?* No. But LPN's may assist the RN with OJT's, as necessary, with oversight by the RN.

[.30 (b) 1)] *Could a revision be made to Rule 116 so that a LPN under the delegation of the RN Nurse-Trainer could cover for the Nurse-Trainer during the Nurse-Trainer's vacation or absence?* No, as LPN's require RN supervision.

[.30 (b) 1)] *Can LPN's do OJT's?* LPN's may assist the RN Nurse-Trainer by reviewing client's medications with staff, reviewing administration practices, or collecting data on individuals for nursing assessments.

[.30 (b) 1)] *Can LPN's still pass medications (in these houses)?* Absolutely. However, the law only allows RN's to authorize and delegate non-licensed direct care staff to pass medications or oversee medication training programs for clients not fully independent in this.

[.30 (b) 1)] *Do all staff have to be authorized if they work in a house?* Yes, if they will be administering medications.

1) Be licensed as registered professional nurse or advance practice nurse in Illinois.

2) Possess two years of clinical registered professional nursing experience within the last five years, at least one of which shall preferably have been in developmental disabilities.

3) Have successfully completed the DHS Nurse-Trainer Training Program.

c) Requests for approval as a Nurse-Trainer shall be submitted in writing, to the DD Clinical Director. The DD Clinical Director shall approve all requests which show substantial

d) The DD Clinical Director shall, upon request, grant conditional approval to a registered professional nurse who fulfills the requirements but has not completed the required nurse-trainer course of instruction. Conditional approval shall be granted for no more than 90 days following the date of conditional approval. The nurse given conditional approval shall not train or authorize non-licensed staff to administer medications, but may direct and monitor, as well as educate and train, previously authorized direct care staff on new medications or dosage changes as shall be required.

See Appendix Q/A # 14.

[.40] *If someone calls off for a particular shift, can another direct care staff pass medications?* Only if that direct care staff has been authorized by the RN nurse trainer for those individuals and their medications in that house (residential setting).

[.40] *How do I address the issue of "fill-in" staff when a DSP calls off? The "fill-in" staff may not be trained in that particular home.* We recommend that you have an "approved" list of staff who have taken the medication administration training for a particular home. Then the only staff who may substitute in that home are those who are on the "approved" list.

[.40 (a)] A Memo, dated 5/19/00 speaking to Rule 116 clarified key points:

- 1) Medication administration tasks may be delegated only by DHS trained RN nurse-trainers to authorized non-licensed direct care staff;
- 2) Only oral and topical medications can be delegated;
- 3) No injections, rectal or vaginal administration routes may be delegated.

[.40 (a)] The department's curriculum, provided in this handout, must be used. The formalized training session is 8 hours (absolutely no less than 7.5 hours). The OJT is based on one hour/client &/or as much time as needed determined by the nurse-trainer. (Forum)

[.40 (b) 1 & 2] *What does the RN nurse-trainer need to complete prior to starting the OJT's and completing the Competency Based Training Assessments (CBTA's) for direct care staff?* There must be a nursing physical assessment, a complete medication and treatment review, and a self-medication assessment done by the RN on each individual/client for whom medications will be administered and evaluated.

[.40 (c)] *How many staff can be authorized by a RN nurse-trainer?* Those numbers are at the discretion of the RN nurse-trainer. The rule does not specify a maximum number.

Section 116.40 Training and Authorization of Non-Licensed Staff by Nurse-Trainers

- a) Only a nurse-trainer may delegate and supervise the task of medication administration to direct care staff.

- b) Prior to training non-licensed staff to administer medication, each nurse-trainer shall perform the following for each individual to whom medications will be administered by non-licensed staff [20 ILCS 1705/15.4 (c)] once they are trained and authorized direct care staff.

- 1) An assessment of the individual's physical and mental status and medical history.
- 2) An evaluation of the medication order(s) and medication(s) prescribed.

- c) Non-licensed direct care staff who are to be authorized to administer medications under the delegation of the registered professional nurse shall meet the following criteria:

[.40 (c)] *Can direct care staff be cross-trained in more than one house?* Yes.

[.40 (c) 3] Functional literacy is 8th grade reading level (only) by the Test for Adult & Basic Education (TABE) test. The nurse trainer need NOT to be the tester.

See Appendix Q/A #15

[.40 (c) 4] *What is included in the "Health & Safety Component" of the DSP core training program?* It consists of CPR/First Aid (through the Red Cross or Heart Association) and the Basic Health & Safety Module of the DSP training (including the classroom portion and OJT's).

[.40 (c) 4] *Must staff take CPR and First Aid before they can administer medications?* Yes. It is part of the DSP training, as well.

[.40 (c) 4] *Are RN nurse-trainers required to teach the basic health and safety portion of the DSP training?* No.

See Appendix Q/A # 16 & 17

[.40 (c) 5] *Do RN nurse trainers have to use the Department's curriculum?* Yes, and it must be a formalized training session for 8 hours (absolutely no less than 7.5 hours) using the DHS curriculum provided in the nurse-trainer sessions.

[.40 (c) 5] *Can LPN's do (teach) the 8-hour training (Medication administration classroom).* No.

[.40 (c) 5] *Can authorized, residential direct care staff go to developmental training (DT) to administer medications for individuals they have been trained to assist?* No. DT/workshop setting must have a licensed nurse administer medications unless the individual is independent in self-medication.

- 1) be age 18 or older;
- 2) complete high school or its equivalency (G.E.D.);
- 3) demonstrate functional literacy;
- 4) satisfactorily complete the Health and Safety component of the Direct Support Persons Core Training Program or a DHS approved equivalent Developmental Disabilities Aide Training Program;
- 5) be initially trained and evaluated by a nurse-trainer in a competency-based, standardized medication curriculum specified by DHS;

[.40 (c) 5)] *If an authorized direct care staff has completed the 8-hour classroom training for Med Admin at one agency, does that carry over when they work at another agency?* The 8-hour classroom training for Med Admin at one agency, does that carry over when they work at another agency? The 8-hour classroom training does not have to be redone. However, the agency and the RN nurse trainer must require written verification from the previous employer that classroom requirements have been met. The OJTs and CBTAs for specific clients and medications may be performed.

[.40 (c) 5)] *Do DSPs need to be retrained if the RN leaves employment?* The new RN can apply for conditional approval from DHS to provide ongoing monitoring and oversight for previously trained staff for a period of 90 days. The new RN may not train or authorize any new staff until attending the DHS Nurse-Trainer course. The staff does not need to have additional training, but it is up to the RN to ensure that previously trained staff continue to perform the task of medication administration in a safe and legal manner.

[.40 (c) 8)] This is done with the nurse-trainer in direct supervision. The CBTA provided in the Nurse-Trainer Training packet is used to complete this requirement for authorization of unlicensed staff.

[.40 (c) 8)] *Regarding OJT – Does the Nurse-Trainer have to assess competency on every med for every client for every staff delegate?* Rule 116 states that 100% competency must be attained by every direct care staff that is authorized by the Nurse-Trainer. They must be competent in every medication for every individual in a specific residence.

See Appendix Q/A # 18

- 6) receive specific additional competency-based training and assessment by a nurse-trainer as deemed necessary by the nurse-trainer whenever a change of medication or dosage occurs or a new individual that requires medication enters the program;
- 7) pass the written portion of the comprehensive examination furnished by DHS based on the information conveyed to them; and
- 8) score 100% on a written or oral competency-based evaluation specifically pertinent to those medications that such staff are responsible to administer.

[.40 (d)] *The time element of training and completing OJT and CBTA?* Medication class must be 8 hours of classroom training. Rule 116 calls for up to 16 hours of OJT to be determined at the discretion of the nurse-trainer. Some people will require more OJT than others before the Nurse-Trainer is comfortable that they can do the task delegated to them. Time spent on the CBTA is included in the OJT time.

[.40 (d)] *Can LPN's do OJT?* LPN's can supplement the RN Nurse-Trainer's training by activities such as reviewing clients' medications with staff, reviewing administration practices. LPN's may also assist RN's by collecting data on clients for the nursing assessments detailed in 116.40 (b) 1).

[.40 (d)] *How many hours are required for OJT?* The department recognizes that the OJT training time will vary and the recommendation of 16 hours was based on the 16 bed home; one hour per client for staff in the home is at the discretion of the RN nurse trainer.

[.40 (e)] *When should in-services be held for staff whose individuals receive new prescriptions?* Training and in-services are determined by the RN Nurse-Trainer and must occur for all new prescriptions.

[.40 (e)] *What are the requirements for the annual retraining of the DSP?* The Nurse-Trainer does an annual evaluation. Any necessary retraining is determined by the Nurse-Trainer at your agency.

- d) Initial competency-based training toward delegation for medication administration shall include:
- 1) Best practice standards related to the rights of individuals, legal and ethical responsibilities, agency procedures and communication pertaining to medication administration.
 - 2) Best practice nursing techniques associated with medication administration.
 - 3) Classes of drugs and their effects and common side-effects.
 - 4) Specific information regarding the individuals to whom such staff will administer medication and the medication such staff will administer.
 - 5) Techniques to check, evaluate, report and record vital signs when such skills are necessary for the safe administration of medication to that individual.
 - 6) A final, individual-specific, competency-based evaluation performed by a nurse-trainer for each medication administered to persons at the program for who such staff provide supports.
- e) Authorized direct care staff shall be re-evaluated by a nurse-trainer at least annually or more frequently at the discretion of the registered professional nurse. Any retraining shall be to the extent that is necessary to ensure competency of the authorized direct care staff to administer medication, [20 ILCS 1705/15.4 (c)] as judged by a nurse-trainer.
- f) Direct care staff who fail to qualify for competency to administer medications shall be given additional education and testing to meet criteria for delegation authority to administer medications. Any direct care staff person who fails to qualify as an authorized direct care staff after initial training and testing must, within three months, be given another opportunity for retraining and retesting. A direct care staff person who fails to meet criteria for delegated authority to administer medication, including, but not limited to, failure of the written test on two occasions, shall be given consideration for shift transfer or reassignment, if possible. No employee shall be terminated for failure to qualify during the three month time period following initial testing. Refusal to complete training and testing required by this Section may be grounds for immediate dismissal. [20 ILCS 1705/15.4 (h)]
- g) No authorized direct care staff person delegated to administer medication shall be subject to suspension or discharge for errors resulting from the staff

[.50] See Appendix Q/A # 21

[.50] *If someone calls off for a particular shift, can another direct care staff pass medications?* Only if that direct care staff has been authorized by the RN nurse-trainer for those individuals and their medications.

[.50 (b)] See Appendix Q/A # 22

[.50 (c)] *Is it true that an RN Nurse-Trainer has to be on call 24 hours a day, 365 days a year?* Yes. Coverage can be done by other health care professionals listed in the rule, but training/retraining of medications can only be done by the RN.

[.50 (c)] *Do we have to have a backup RN if we have our own RN?* An RN must be on duty or on call at all times if authorized staff are administering medications. If this is not possible, another trained Nurse-Trainer may assist.

[.50 (c)] *Can a LPN under the delegation of the RN Nurse-Trainer cover for the Nurse-Trainer during the Nurse-Trainer's vacation or absence?* No LPN's require RN supervision.

[.50 (c)] *Problems with arranging 24 hours on-call. Could someone else do the phone report and the nurse-trainer send the written report when she/he is back on duty?* ● Contact with a neighboring agency to share nurse-trainer on-call time. ● Hire a nurse that is willing to work just as an on-call persons for med admin PRN. ● Errors have to be reported to IDPH within 24 hours by phone (this has been changed). ● Have 2 nurses on staff and trade call.

person's acts or omissions when performing the functions unless the staff person's actions or omissions constitute willful and wanton conduct [20 ILCS 1705/15.4 (i)].

- h) Authorization of staff to administer medication shall be revoked if, in the opinion of the registered professional nurse-trainer, the authorized direct care staff person is no longer competent to administer medication. [20 ILCS 1705/15.4 (c)] The degree of retraining and reassessment of competency should occur at the discretion of the nurse-trainer.
- i) Clear documentation of training, retraining, and evaluation shall be kept in each staff or contractual person's personnel file by each agency where authorized direct care staff are employed.

116.50 Administration of Medications

- a) Medications shall be administered in accordance with the Mental Health and Developmental Disabilities Administrative Act [20 ILCS 1705] and the Illinois Nursing and Advance Practice Nursing Act [225 ILCS 65].
- b) Non-licensed staff shall not administer any medication in an injectable form.
- c) A registered professional nurse, advanced practice nurse, physician licensed to practice medicine in all of its branches, or physician assistant shall be on duty or on call at all times in any program covered by this Part [20 ILCS 1705/15.4 (j)]

See Appendix Q/A # 23 through 25

[.50 (d)] *Can staff initiate a PRN? for example, if an individual is non-verbal and he is hitting his head, can staff offer Tylenol for a headache?* PRN's must be ordered by a physician, including the listing of signals or symptoms that trigger its use. The PRN order must be part of the individual protocol.

[.50 (d)] *Do the direct care staff have to call the nurse for each PRN?* PRN's should be written in conjunction with the physician so that no professional judgment or assessment is needed by non-professional staff. When an individual is able to communicate his/her need for the PRN in some fashion, and if the PRN has a protocol, authorized staff may administer it. ICF/DD's have additional requirement for PRN use (Refer to Rule 350.)

[.50 (d)] *Do the direct care staff have to call me each time for PRN's* PRN's should be written in conjunction with the physician so that the parameters are clear enough that no judgment or assessment is needed..... individuals must be able to communicate in some fashion their need for the PRN.

[.60] *Aren't we just making individuals less independent by having this rule that allows direct care staff to pass medications?* The intent of Rule 116 was to allow individuals who were truly incapable of self-medication to remain safely in the community. It was never intended to take individuals back to a level where they were simply being administered medication. We do, however, need to provide oversight even for those who are capable to self-medicate or in a program of self-medication to ensure their safety.

d) Authorized direct care staff shall not administer PRN medications unless there is a written protocol approved by a nurse-trainer and prescribing practitioner for each individual and for each medication. A written protocol shall include the following information:

- 1) the name of the individual;
- 2) the name, route, and dosage form of the medication;
- 3) dosage or quantity to be taken;
- 4) frequency or time(s) of administration;
- 5) conditions for which the medication may be given;
- 6) contraindications for the medications;
- 7) a maximum or stop dosage;
- 8) any necessary special directions and precautions for the medication's preparation and administration;
- 9) common severe side or adverse effects or interactions and the action required if they occur; and
- 10) proper storage.

e) A facility may stock for use as PRN medications, and in accordance with subsection (d) above, only drugs which are regularly available without prescription at a commercial pharmacy, such as: uncontrolled cough syrups, laxatives, and analgesics. These shall be given to an individual only upon the written order of the physician, dentist, or podiatrist; shall be administered from the original containers and shall be recorded in the individual's medication administration record (MAR).

Section 116.60 Medication Self-Administration

- a) As part of the normalization process, in order for each individual to attain the highest possible level of independent functioning, all individuals shall be permitted to participate in their total health care program. [20 ILCS 1705/15.4 (d)]. Every program shall include, but not be limited to, individual training in promoting wellness, prevention of disease and medication self-administration procedures.
- 1) Every program shall adopt written policies and procedures for assisting individuals in obtaining preventative health and medication self-administration skills in consultation with the registered professional nurse. [20 ILCS 1705/15.4 (d)]
 - 2) Individuals shall be evaluated to determine their self-administration of medication capabilities by a nurse-trainer through the use of DHS required, standardized screening and assessment instruments.
 - 3) When the results of the screening and assessment indicate an individual not to be independently capable to self-administer his or her own medications, programs shall be developed in consultation with the Community Support Team (CST) or Interdisciplinary Team (IDT) to

provide individuals with [20 ILCS 1705/15.4 (d)] medication self-administration training as identified in each individual's treatment/service plan.

- b) Each individual shall be presumed to be competent to self-administer medications if he or she has been determined to be:
 - 1) capable by a registered professional nurse or advanced practice nurse;
 - 2) approved to self-administer medication by the individual's Community Support Team (CST) or Interdisciplinary Team (IDT); and
 - 3) authorized by a written order of a physician licensed to practice medicine in all of its branches.
- c) Training of individuals to self-administer medication shall minimally include instruction, for each medication prescribed, in the following areas:
 - 1) name of medication or identification within the existing agency pharmacy protocol;
 - 2) dosage or quantity to be taken;
 - 3) route of administration;
 - 4) frequency or time(s) of administration;
 - 5) purpose of medication, special instructions, common side-effects and potential consequences of not taking the medication or of no taking the medication properly; and
 - 6) when to seek medical assistance and any action to be taken in the event of a missed dose, medication error, or adverse drug reaction.
- d) When requested to do so by an individual, authorized direct care staff may assist an individual in the self-administration of medications by taking the medication from the locked area where it is stored and handing it to the individual. If the individual is physically unable to open the container, a staff member may open the container for the individual. Agency staff may also assist physically impaired individuals, such as those who have arthritis, cerebral palsy, or Parkinson's disease, in the removal of the medication from the container and in consuming or applying the medication.
- e) Each individual shall remain under observation by authorized direct care staff and be assisted by the staff to correct or prevent medication error(s) and to safeguard against adverse drug reactions. All such observation and assistance shall be noted in the progress section of the individual's clinical record.
- f) Individuals specifically determined to be competent, by a physician who has issued a written order, to self-administer their own medications may maintain possession of the key or combination of the lock to their own medication storage area. A duplicate key or a copy of the combination shall be kept by the program in a secure location for emergency use, such as if the individual should lose or misplace the key or forget the combination.

See Appendix Q/A #26

See Appendix Q/A #27

[.60 (g)] While the Rule does not require an MAR, it does require supervision of self-administration. To get show this supervision, some sort of medication tracking document is necessary.

[.60 (g)] *What should staff do if individuals who are capable of going into the community on their own, purchase over the counter medication with their own money?*

A medication made available over-the-counter does not make it any less of a medication. Medication monitoring is part of the nurse's assessment of an individual's health status. A physician must sign an order for any medications purchased over-the-counter.

See Appendix Q/A #28 through 29

[.70 (a)] *Can someone else do the phone report if the nurse trainer is off? Can the nurse send in the written report when s/he is back on duty?* No. You can either contract with a neighboring agency to share nurse-trainer on-call time, hire a nurse that is willing to work as an on-call person for med admin on a PRN basis, or have two nurses on staff and they can trade on-call duties.

- g) A medication administration record need not be kept for those individuals for whom the attending physician has given permission to have access to their own medications and to be fully responsible for taking their own medications.

Section 116.70 Medication Administration Record and Required Documentation

- a) All medications, including patent or proprietary medications (e.g. cathartics, headache remedies, or vitamins, but not limited to those) shall be given only upon the written order of a physician, advanced practice nurse, or physician assistant. Rubber stamp signatures are not acceptable. All such orders shall be given as prescribed by the physician and at the designated time. Telephone orders may be taken by a registered professional nurse or licensed practical nurse. All such orders shall be immediately written on the individual's clinical record or a "telephone order form" and signed by the nurse taking the order. These orders shall be countersigned or documented by facsimile prescription by the physician within ten working days.
- b) Medication Administration Record
- 1) An individual medication administration record shall be kept for each individual for medications administered and shall contain at least the following:
 - A) the individual's name;
 - B) the name and dosage form of the drug;
 - C) the name of the prescribing physician, physician assistant, dentist, podiatrist, or certified optometrist;
 - D) dose;
 - E) frequency or time(s) of administration;
 - F) route of administration;
 - G) date and time given;
 - H) most recent date of the order;
 - I) allergies to medication; and

[.70 (b) 3 & 4)] *Can direct care staff write on the Medication Administration Report (MAR)?* Direct care staff may not transcribe physician orders onto the MAR. They may write "d/c", enter times, etc., at the direction of the RN nurse-trainer.

See Appendix Q/A # 30 through 32

[.70 (c)] *Why is there such an emphasis on medication error reporting?* Previously there was no accountability for medication errors in community-based settings. The Rule is designed to ensure the safety of all the individuals in the community-based programs.

[.70 (c)] *Is a missing initial really considered a medication error that has to be reported?* Yes, it is a medication documentation error and must be reported.

[.70 (c)] *Medication errors on out-of-facility visits.* We all want to avoid medication errors any place. It is not the responsibility of the agency/facility if an error occurs outside the agency. You have no control over the medication if it is out of your hands. It would be important to maintain some documentation in regards to this so

J) special considerations.

- 2) The medication administration record for the current month shall be kept with the medications or in the individual's clinical record. If logs are kept in the individual's clinical record, the record shall be present when and where the medications are taken so that the appropriate notation can be made in the log.
- 3) The medication administration record shall be completed and initialed immediately after the medication is administered by the authorized direct care staff. Each medication administration record shall have a section which contains the full signature and title of each individual who initials the medication administration record.
- 4) All changes in medication shall be noted on the medication administration record by a licensed practical nurse, registered professional nurse, advance practice nurse, pharmacist, physician, physician assistant, dentist, podiatrist, or certified optometrist and reported to the registered professional nurse in charge of the program prior to the next dose.
- 5) Individual refusal to take medication(s) shall be noted in the medication administration record. A progress note by authorized direct care staff shall be written in the individual's clinical record indicating the reason(s) for refusal and the registered professional nurse shall be notified.
- 6) For individuals who are independently self-administering medications, no medication administration record shall be required. However, any medication which individuals take shall be listed in their clinical records, including dosage, frequency, and identity of the prescribing physician, physician assistant, dentist, podiatrist or certified optometrist. Each agency shall develop and implement a quality assurance system to ensure that self-administered medications are taken in accordance with prescribed orders.

- c) In the event of a medication error, authorized direct care staff shall immediately report the error to the registered professional nurse, advance practice nurse, pharmacist, physician, physician assistant, dentist, podiatrist, or certified optometrist to receive direction on any action to be taken. All medication errors shall be documented in the individual's clinical record and a medication error report shall be completed within eight hours or before the end of the shift in which the error was discovered, whichever is earlier. The medication error report shall be sent to the nurse-trainer for review and further action. A copy of the medication error report shall be maintained as part of the agency's quality assurance program. Medication errors must be reported to the DHS Bureau of Quality Enhancement (or the Illinois Department of Public Health Regional Office if an individual of an ICF/DD-16 is involved) in accordance with written instructions from the Department's Bureau of Quality Enhancement or DPH's rules (77 Ill Adm. Code 350). All medication errors are subject to review by DHS or DPH, whichever is applicable. Medication errors which meet the reporting criteria pursuant to the Department's rules on Office of Inspector General Investigations of Alleged Abuse or Neglect or Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50) shall be reported to the Office of Inspector General.

that teaching could occur and errors could be reduced or eliminated.
See Appendix Q/A #33

[.70 (e)] *Do controlled drugs need to be counted on every shift?* Yes, there must be an accounting for these drugs by the direct care staff. This should be reviewed on a monthly basis by the RN trainer.

See Appendix Q/A #34.

[.80 (a)] *Do controlled medications need to be double locked?* All medication must be locked. Controlled substances, however, must be counted at the end of each shift. There is no provision for double locking in the rule.

- d) In the event of suspected drug reaction, authorized direct care staff shall immediately report the signs and symptoms to the registered professional nurse, advance practice nurse, pharmacist, physician, physician assistant, dentist, podiatrist, or certified optometrist to receive direction on any action to be taken. All adverse drug reactions shall be documented in the individual's clinical record and an adverse drug reaction report shall be completed within eight hours or before the end of the shift in which the reactions was discovered, whichever is earlier. The adverse drug reaction report shall be sent to the prescriber and the nurse-trainer for review and further action. A copy of the adverse drug reaction report shall be maintained as a part of the agency's quality assurance program.
- e) An inventory and a record of use of controlled substances shall be maintained by the registered professional nurse in the program, and each substance shall require a separate sheet indicating the:
 - 1) name of the individual;
 - 2) name of the prescriber;
 - 3) serial number of the prescription;
 - 4) name of the drug and strength;
 - 5) amount used;
 - 6) amount remaining;
 - 7) time and date administered;
 - 8) name of the individual who administered the medication; and
 - 9) documentation of a shift count done by authorized direct care staff. Any discrepancies shall be reported to the nurse-trainer for review and action in accordance with written policy.

Section 116.80 Storage and Disposal of Medications

- a) All drugs shall be stored in locked compartments or within the locked medicine container, cabinet or closet.
- b) Access to medications shall be limited to licensed and authorized direct care staff. Each program shall maintain an up-to-date list of authorized direct care staff on its premises.
- c) Each program shall have a written procedure for safeguarding medications kept in an individual's room or possession and shall require medications to be stored when individual safety cannot otherwise be assured.

See Appendix Q/A #35

[.80 (d)] *Can I repack medication for outings?* Medication must remain in their original container until they are taken or administered. Re-labeling of medication falls under the pharmacy practice act as dispensing and may not be done by anyone other than a pharmacist or physician.

[.80 (d)] *Can nurses repack medications?* No. Nurses may administer medications, not dispense them.

d) All medications shall be stored in their original containers.

e) All prescription medications which are given to individuals at the direction of the physician, registered professional nurse, advance practice nurse, pharmacist, physician assistant, dentist, podiatrist, or certified optometrist shall have a label with the same information as would appear on a pharmacy label in accordance with Section 22 of the Illinois Pharmacy Practice Act [225 ILCS 85] to show:

- 1) the name and address of the pharmacy where the prescription is sold or dispensed;
- 2) the name or initials of the person authorized to practice pharmacy;
- 3) the date on which the prescription was filled;
- 4) the name of the patient;
- 5) the serial number of the prescription as filed in the prescription files;
- 6) the last name of the practitioner who prescribed the prescriptions;
- 7) the directions for use as contained in the prescriptions; and
- 8) the proprietary name or names or the established name of the drugs, the dosage, and the quantity.

f) Disposal of all medications shall be in accordance with federal and state laws.

Section 116.90 Individual Health Supports and Assessment

- a) The registered professional nurse shall assess an individual's health status at least annually or more frequently at the discretion of the registered professional nurse.
- b) A physician shall assess an individual's health status at least annually or more frequently at the discretion of the physician or at the request of the agency or the registered professional nurse.

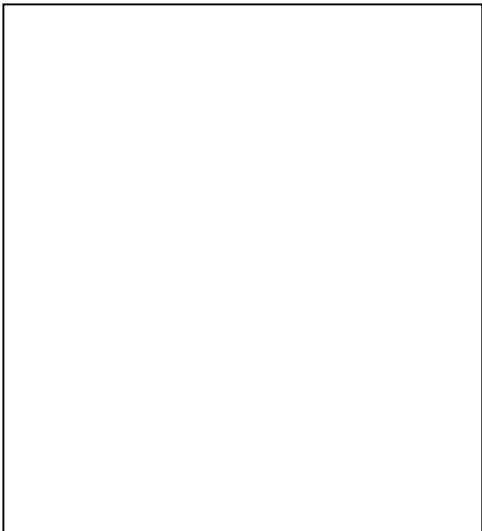
Section 116.100 Quality Assurance

- a) A registered professional nurse, advance practice nurse, licensed practical nurse, pharmacist or physician shall review the following for all individuals.

- 1) medications orders;
- 2) medication labels and medications listed on the medication administration record to ensure that they match physician orders; and
- 3) medication administration records (for persons who are not self-medicating) to ensure that they are completed appropriately for:
 - A) medication administered as prescribed;
 - B) refusal by the individual; and
 - C) full signatures provided for all initials used.
- b) Reviews shall occur at least quarterly, but may be done more frequently at the discretion of the registered professional nurse and/or advanced practice nurse.
- c) A quality assurance review of medication errors for the purpose of monitoring and recommending corrective action shall be conducted within seven days of occurrence and included in the annual review.
- d) Documentation of the review and the review date shall be retained for at least five years.
- e) All quality assurance records shall be confidential and may only be disclosed in accordance with the provisions of Part 21 of Article VIII of the Code of Civil Procedure [735 ILCS 5/8-2101 through 8-2105].
- f) If Nothing in this Part shall limit or restrict the reporting of medication errors as possible abuse or neglect or the investigation by the Office of Inspector General of possible abuse or neglect in accordance with the Department's rules on Office of Inspector General Investigations of Alleged Abuse or Neglect and Deaths in State-Operated and Community Agency Facilities (59 Ill. Adm. Code 50).

Section 116.110 Administrative Requirements

- a) Written policies and procedures shall be developed by each agency that include:
 - 1) Provisions for on-going supervision and monitoring of authorized direct care staff.
 - 2) Provision for annual review and any necessary retraining of authorized direct care staff in theory and practice of medication administration.
 - 3) Provisions for a systematic review of all medication errors, adverse drug reactions, and incidents to identify contributing factors and plan corrective action.
 - 4) Provisions for recording and reporting of all instances of retraining and retesting for failure to qualify as an authorized direct care staff.
- b) Each program shall have written policies and procedures to include the governing of:



- 1) distribution of medications, including controlled substances, and persons authorized to distribute medications;
 - 2) administration of medications;
 - 3) quality assurance medication review;
 - 4) storage and safekeeping of medications;
 - 5) disposal of medication, including controlled substances; and
 - 6) training, review and any necessary retraining of authorized direct care staff.
- c) Policies and procedures shall be consistent with applicable rules, regulations, and federal and State law.
- d) Each program shall have a copy of all policies and procedures related to medication on file and readily available to all programs at all times.

Appendix – Q/A that were too long to be included in the column format. Questions are in *italics* and Answers are in unmodified type.

1. Q: [.10] *Are there interpretive guidelines for Rule 116? If so, we would like a copy; if not, they need to be developed and issued to agencies and surveyors so everyone is on the same page.*

A: Rule 116 is already written in a clear and straightforward manner. Further interpretive guidelines will, in the Department's opinion, send an intrusive message. The Department has consistently promoted the premise of the law and Rule 116, which promulgates professional judgment of the Nurse-Trainer and the Community Support Team, along with encouraging the development of agency specific policy and procedure decisions.
2. Q: [.10] *How does Rule 116 apply to the foster care model homes?*

A: The rule applies to residential settings of 16 or fewer individuals with developmental disabilities, and it must be funded or licensed by DHS or IDPH. Unless these criteria pertain to your program, Rule 116 does not apply. The agency has a choice of having licensed nurses administer medications or hiring and training a registered nurse to teach staff to administer medications. If your program does not fall into all of these categories, then Rule 116 does not apply....
3. Q: [.10] *How is the state going to react to a class action law suite in behalf of clients that no longer can participate in offsite activities because there is not a med certified staff available to go with them to give out meds?*

A:
 - First, if it is not critical that a medication be given at a particular time, the nurse can contact the physician for an order to either miss a dose, delay a dose or administer the dose early.
 - Second, if the individual can administer independently and they go on routine outings, the pharmacy can package a small number in a bottle that is properly labeled and the individual can take the bottle with them and administer their own meds.
 - Third, the pharmacist and/or nurse should review medications to eliminate unnecessary drugs and assess for medications that can be given in a once-a-day dosing.
 - For those individuals that must take their medication at a particular time and not miss doses, schedule their outings, or your staff, so that an authorized DSP is available to accompany them.
 - Normalization and participation in community activities requires judgment and a balanced approach relative to safety, the obligation to meet medical and nursing care needs, choice and resident rights.

Q: [.20] Administer or Administration – *Rectal and vaginal medications and procedures (i.e. enemas, douches, suppositories, etc).* – Under the definition “administer” in Rule 116, it states, [see definition of “Administer” or “Administration”]. A letter was also sent by DHS in June that states. “To help clarify some areas of confusion, please note the Department’s policy on the following key points:....only oral and topical medication can be delegated: no injections, rectal or vaginal administration routes may be delegated.”

Nothing in Rule 116 states that only nurses can give GI tube feedings, enemas, douches, etc., but that’s what has been communicated to Nurse-Trainers. This point needs further discussion and clarification; there is a difference between a water or fleets enema and prescription medications being administered via the rectum; a difference between a nutritional feeding and giving prescription medications through a G-tube; and a difference between a hygiene douche and a medication (i.e. pill, cream, ointment, etc.) being administered in the vagina.

At the last meeting the Master Nurse-Trainer was asked, “if authorized staff could administer meds into a GI tube.” The response was, “That is still in legal.” A prompt clarification on all three issues is needed.

Having recently had family in the hospital, I might add that nurses do not complete all of these procedures even in a hospital.

A: Your quotes from Rule 116 and my May 19, 2000 memo regarding the Department’s policy on rectal or vaginal medication administration were accurate. Your understanding of Rule 116 appears correct. The intent of the legislation and Rule 116 are reasonably clear and cover only oral and topical medication as noted in the training. The May 19th memo was written to underline the understanding of that intent and in response to requests for clarification. Rule 116 does not state that only nurses can give GI tube feedings, enemas, or douches. Rule 116 was not intended to address treatments that could be identified in a nursing plan of care. Treatments, such as GI tube feedings, non-medicated enemas, and suctioning are not expressly restricted by Illinois law, as is medication administration, however that does not mean they can be automatically delegated.

Based on a nurse’s professional judgment, in conjunction with the provisions of the Illinois Nursing and Advanced Practice Nursing Act, and delegation guidelines published by professional nursing organization, like the Illinois Nurses Association and the Developmental Disabilities Nurses Association, certain treatments either may or may not be delegated to a non-licensed staff person. Any delegation of care, such as specific treatments, is determined by the professional nurse, with consideration for the level of supervision that the RN will be able to provide, along with other factors. In acute care settings, RN’s are immediately available and provide direct supervision, as defined in the Illinois Nursing and Advance Practice Nursing Act, which may impact on their delegation practices.

DHS clinical staff recommends that within individual DD settings some internal process should be in place that serves as guidelines for delegation of nursing care and treatments. A number of steps should occur. The nurse should assess the individual and the potential nursing care needs, have a written plan of care, identify the skill level required to carry out the treatments, determine if direct care staff has the knowledge and skill level required and/or can be completely trained in these skills, then develop, implement and evaluated the training of non-licensed staff to carry out the nursing treatments. These aspects should be well documented.

5. Q: [.20] Administer or Administration? – *Can non-licensed staff give GI tube feedings, enemas, douches, etc.?*

A: Treatments, such as GI tube feedings, non-medicated enemas, and suctioning, are not restricted by Illinois law. However, that does not mean they can be automatically delegated to non-licensed staff. It is up to the Nurse-Trainer to train capable staff, based on a nurse’s professional judgment. Any delegation of care is determined by the professional nurse, with consideration for factors, such as the level of supervision that the RN will be able to provide.

DHS clinical staff recommend that within individual DD settings some internal guidelines should be in place for delegation of nursing care and treatments. The nurse should assess the individual and the potential nursing care needs, have a written plan of care, identify the skill level required to carry out the treatments, determine if direct care staff have the knowledge and skill level required and/or can be competently trained

in these skills. Then the Nurse Trainer must develop, implement and evaluate the training of non-licensed staff to carry out the nursing treatments. This should be well documented.

6. Q: [.20] Authorized direct care staff – *Do I have to totally retrain newly hired DSP's in medication administration if they were already trained by another agency?*
- A: If your agency has the new staff person's permission, you can ask the former employer for documentation of successful completion of Med Admin training. The information should include verification of attendance at the 8-hour Med Admin class taught by a DHS Nurse-Trainer using DHS Medication Administration curriculum and a copy of the person's completed test showing a grad of at least 80%. In addition, staff must errorlessly perform the Medication Administration OJTs for the specific individuals to which the staff will be administering medications. The Nurse-Trainer determines whether the trainee successfully passes the CBTAs.
7. Q: [.20] Authorized direct care staff – *If I have a new employee who completed Medication Administration training at another agency, would she have to take another TABE? Would we be reimbursed for the test and training?*
- A: A new employee is not required to retake the 8 hour Medication Administration class if you can obtain proof of attendance at that training. They are also not required to repeat the TABE if you have proof of successfully completing the above training. However, reimbursement for completing all of the Medication Administration training may be obtained by a new organization training a new employee, regardless of the employee's history elsewhere.
8. Q: [.20] Authorized direct care staff – *Are these authorized direct care staff certified?*
- A: Authorized direct care staff are **authorized**. The term "certified" may convey a level of independent functioning inconsistent with what these staff are able to do. Authorized direct care staff administer medication or oversee medication administration training programs carried out by clients not fully independent in self-administration of their own medication under the delegation and supervision of the DHS approved RN. The **authorization** of staff pertains to specific individual clients in specific houses (DD residential settings) for specific medications prescribed by a licensed practitioner (i.e. physician). Authorization of staff must follow the guidelines set forth in Rule 116.
9. Q: [.20] Delegation – *RNs are feeling very threatened by the possibility of losing their licensure because of authorized staff making medication errors. Revocation of licensure is not mentioned in Rule 116, but nurses from our agency feel very threatened. The DHS med administration curriculum states in the training material to be presented to authorized staff that traditionally the individual with the highest level of licensure is held responsible for the outcome of all actions performed by those responsible to her/him. It also states in the Rule that the RN retains professional accountability and that the direct care staff will not be held blameless. These things, when communicated in training to authorized staff, could certainly give the authorized staff the impression that it does not matter if they make a medication error, that the RN will be responsible for their actions. That is a threat to nurses and requires clarification.*
- A: ...a Nurse-Trainer has to be personally capable of delegation and supervising non-licensed staff from a distance. Not all RN's will want to do this. Please note, however, that the issue of delegation is already well addressed by professional nursing associations and is a practice accepted by them. The Rule reflects that current professional standard, which has not been altered by our interpretations.
10. Q: [.20] Delegation – *RN's are feeling very threatened by the possibility of losing their licensure because of authorized staff making medication errors. Revocation of licensure is not mentioned in Rule 116.... The DHS med administration curriculum state...the individual with the highest level of licensure is held responsible... It also states... that the RN retains professional accountability...*
- A: ...a Nurse-Trainer has to be personally capable of delegation and supervising non-licensed staff from a distance. Not all RN's will want to do this. Please note, however, that the issue of delegation is already well addressed by professional nursing associations and is a practice accepted by them. The Rule reflects that current professional standard, which has not been altered by our interpretations.

11. Q: [.30 (b) 1)] *Can the Med Admin Training be outsourced to another qualified Nurse-Trainer, that is, another Nurse qualified to teach, but not working with the Agency in that capacity?*
- A: The 9-hour class room training may be taught by any Nurse-Trainer on file with DHS as an approved Nurse-Trainer. The....RN Nurse Trainer must use the Department's curriculum... provided in the Nurse-Trainer class and the class must be 8 hours (at least 7.5 hours) in length. The Nurse Trainer(s) who complete the OJT and CBTA activities with staff at an agency/home must also perform an assessment of each client's physical and mental status and medical history and an evaluation of the medication order(s) and medication(s) prescribed, for all clients for whom medication administration tasks are delegated. Additionally, authorized non-licensed staff require ongoing RN supervision and training on new medications and/or changes in medication orders. Therefore, agencies are not limited in creating relationships with approved DHS Nurse-Trainers, as long as the required components of Rule 116 are met for their clients and staff.
12. Q: [.30 (b) 1)] *Why can't LPNs be more involved in the training?*
- A. In the Illinois Advanced Practice and Nurse Practice Act, RN's have powers that LPN's do not. In this act, RN's may delegate nursing care, LPN's cannot. RN's may identify nursing diagnoses (problems) and initiate a nursing plan of care, LPN's may assist the RN, collect assessment data and contribute to the plan of care, but LPN's cannot perform these functions independently. LPN's are required to be supervised by an RN. An LPN's involvement in training and carrying out nursing plans of care for clients must be determined by the RN, consistent with the practice act. LPN's cannot be Nurse-Trainers.
13. Q: [.30 (b) 1)] *How do you recommend community providers deal with the staff turnover rate and the medication administration issue? RNs' are being required to train all staff on all meds and continue to perform their already required duties. I am concerned about the ability to continue to provide quality services as well as keep up with the continuous training. I would like to be able to utilize LPN services to assist the RNs' in training.*
- A: These are basic staff issues, not unfamiliar to agency operations.
14. Q: [.40] *What is the point of being certified for giving meds when most people have been giving meds (or overseeing residents) for years, if you have annually be in-serviced on the subject?*
- A: According to Illinois law, medication administration has always been the responsibility of licensed nurses. (RN's and LPN under the direction of a Registered Nurse). When individuals started coming out of state institutions and moving into community settings, it was thought that individuals would be "self-medicating" and that staff would only be offering supportive assistance. the limes of professional responsibility began to blur as time went by. When HCFA came to Illinois in 1999, it was very clear to them that agencies and staff were in violation of the Illinois Nursing Practice Act. HCFA cited the State of Illinois for violating our own laws. Experience alone does not qualify a non-licensed person to administer medications. They put a freeze on all Federal money to support developmentally disabled individuals living in the community until such time as Illinois came up with an acceptable plan of correction. This loss was devastating to the state. Rule 116 is Illinois's response to the HCFA survey. If amends the Illinois Nursing Practice Act to allow for RN Nurse-Trainers to delegate the task of medication administration to certain qualified and trained support staff. The RN Nurse-Trainer retains professional responsibility and judgment. It is important to remember that this is a voluntary program. Agencies may still hire licensed nurses to administer medications.
15. Q: [.40 (c) (4)] *Is it necessary to require that CPR and First Aid be completed before medication training is implemented?*
- A: CPR and First Aid are part of the Health and Safety component of the Direct Support Persons Care Training Program. Satisfactorily completing the Health and Safety component of the Direct Support Persons Core Training Program is listed in Rule 116's required criterion for authorization of non-licensed staff to administer medications under the delegation of the RN.
16. Q: [.40 (c) (5)] *If I have a new employee who completed Medication Administration training at another agency, would she have to take another TABE? Would we be reimbursed for the test and training?*

- A: A new employee is not required to retake the 8 hour Medication Administration class if you can obtain proof of attendance at that training. They are also not required to repeat the TABE if you have proof of successfully completing the above training. However, reimbursement for completing all of the Medication Administration training may be obtained by a new organization training a new employee, regardless of the employee's history elsewhere.
17. Q: [.20] Authorized direct care staff – *Do I have to totally retrain newly hired DSP's in medication administration if they were already trained by another agency?*
- A: If your agency has the new staff person's permission, you can ask the former employer for documentation of successful completion of Med Admin training. The information should include verification of attendance at the 8-hour Med Admin class taught by a DHS Nurse-Trainer using DHS Medication Administration curriculum and a copy of the person's completed test showing a grad of at least 80%. In addition, staff must errorlessly perform the Medication Administration OJTs for the specific individuals to which the staff will be administering medications. The Nurse-Trainer determines whether the trainee successfully passes the CBTAs.
18. Q: [.40 (d)] *Does the training need to be specific to each medication and each resident? This is extremely cumbersome to implement when the "act of giving medications" needs to be trained.*
- A: (Yes.) The medication administration training is much more than just the act of handing a pill to an individual and having the swallow it. The authorized DSP must know how each medication will, or could, act/react on each individual based on that individual's specific diagnoses or condition. The entire med. adm. program was designed to be resident specific.
19. Q: [.40 (e)] *Do Med Techs need to be retrained when the RN leaves employment? If the RN leaves are the Med Techs still certified?*
- A. First, we must stress that this is **not** a "Med Tech" program and the staff are **not** "Certified". When decisions were made on how to address HCFA's concerns, it was decided that Illinois would go to an "Authorization" program. Medications are the responsibility of the Registered Nurse. The RN attends training to become a Nurse-Trainer and then may delegate the task of medication administration to certain qualified and trained staff, in certain specific settings. The RN retains professional judgment and responsibility. The authorization is given verbally. If an RN leaves an agency, the agency must provide a new RN to fulfill the responsibilities of Rule 116. The new RN can apply for conditional approval from DHS to provide ongoing monitoring and oversight for previously trained staff for a period of 90 days. The new RN may not train or authorize any new staff until she attends the DHS Nurse-Trainer course. The staff does not need to go to additional training when there is a new Nurse-Trainer, but it is up to the RN to insure that the previously trained staff continue to perform the task of medication administration in a safe and legal manner.
20. Q: [.40 (e)] *If I have a new employee who completed MAR training at another CILA, would she have to take another TABE? Would we be reimbursed for the test and training?*
- A: A new employee is not required to retake the 8 hour Medication Administration class if you can obtain proof of attendance at that training. They are also not required to repeat the TABE if you have proof of the above training, as they would have had to pass in order to attend the training. It is my understanding that reimbursement is base on attendance. If they attend the class or take the TABE, if it is reimbursable, you will be reimbursed.
21. Q: [.50] *Can someone work without DSP training if with another DSP or if they don't give meds?*
- A: Rule 116 doesn't address the first part of this question. That is covered in Rule 115. The Basic Health and Safety component is part of the total DSP training that all staff should have, whether they will eventually take the Medication Administration class or not. If a trained, but unauthorized staff person works in a house with an authorized staff person, it must be understood that the non-authorized staff person cannot administer medications or assist the individuals with their self-medication programs.

22. Q: [.50 (b)] *Are there special considerations for staff approval for Epi-pens, suppositories for seizure activity?*

A: There are no special considerations for an approval process. However, in a true anaphylactic reaction there is a need for quick emergent action so the emergency medical system must be activated and someone in the house should be trained in the basics of how an EpiPen works. Administration of suppositories for seizure activity is excluded along with other rectal medications. If a seizure develops into an emergency situation the emergency medical system must be activated and support given to the individual until their arrival.

23. Q: [.50 (d)] *A Nurse Trainer recently asked if staff may initiate a PRN. For example, if an individual is non-verbal and they are hitting their head, can staff offer Tylenol for a headache? They were told that behavior/ communication/gesture dictionary, in such instances, would be appropriate. Please clarify this point in writing.*

A: Rule 116 clearly identifies the use of PRN's in Section 116.50 Administration of Medications. The guidelines for PRN use can be found there. The signals or symptoms to trigger the use of such medication would be part of the individual protocol, as noted in Section 116.50 d) "Conditions for which the medication may be given."

24. Q: [.50 (d)] *It is very difficult and time consuming to develop a written protocol, as required in Rule 116, for every PRN someone might need (i.e. "patient or proprietary medications"). It is unreasonable to call the doctor every time someone needs cough syrup. Nurse-Trainers have been told at training meetings, that anything medicated needs a doctor's order. It seems ridiculous to require a prescription for things such as medicated shampoo, Carmex, peroxide, rubbing alcohol, Neosporin, etc. That would mean staff could not utilize first aid kits or apply even minor first aid. It also makes it impossible for agencies to be proactive in preventing illness and makes it much more difficult for individuals with disabilities to make choices regarding their own health care. It takes away some of their independence and opportunities for choice.*

A: The format for each written PRN protocol described in Rule 116 is little more than the information commonly found on the Medication Administration Record (MAR) and is not intended to be overly complicated. Since each protocol is approved by a Nurse-Trainer and prescribing practitioner, the physician would not need to be called, as the order would have been written at the same time that the protocol was approved. In this way, expected PRN's such as first aid Neosporin ointment would already be a written physician order and a written PRN protocol. Supporting independence responsibility is an individually based process.

25. Q: [.50 (d)] *It is very difficult and time consuming to develop a written protocol for every PRN someone might need (i.e. patient or proprietary medications). It is unreasonable to call the doctor every time someone needs cough syrup. Nurse Trainers have been told at meetings that all medications need a doctor's order (even over the counter medications).*

A: Since each protocol is approved by a Nurse-Trainer and the prescribing practitioner, the physician would not need to be called. The physician's order should have been written at the same time the protocol was approved. Therefore, expected PRN's, such as first aid ointment, should already be written in a physician order and a PRN protocol. Other items, such as shampoo, peroxide, or alcohol are not medications. These are not meant to be included as a PRN, unless a particular situation becomes a medical concern. The nurse must provide guidance to non-licensed direct care staff to improve the overall quality of health related supports.

As to shampoo, peroxide, alcohol, these are not specific medications and their use, just as basic first aid, may not necessarily be a medical concern. These are not meant to be included, unless a particular situation rises to the level of a medical concern. The guidance that the nurse might provide in these cases would serve to improve the overall quality of the health related supports provided by non-licensed direct care staff.

26. Q: [.60 (d)] *Can unauthorized staff supervise individuals who have their meds locked in their rooms?*

A: The only staff that should be supervising medication administration are staff who have been trained and authorized by the RN Nurse-Trainer. Individuals, who have been determined by the DHS Self-Medication Screening and Assessment (now the Self-Administration of Medication Assessment [SAMA]) to be independent and who have an order by their physician saying that they may independently take their medications, do not need anyone supervising their daily medications. They do not need to have a Medication Administration Record. However, the agency must have some sort of quality assurance system in place to make sure that self-administering individuals continue to safely self-administer medications.

27. Q: [.60 (e)] *Can non-certified people supervise individuals who have their meds locked in their rooms?*

A: The only staff that should be supervising medication administration is staff that have been trained and authorized by the RN Nurse-Trainer to perform this task. Individuals that have been determined by the DHS Self-Medication Screening and Assessment (no SAMA, my note) to be independent in their medication administration, and who have an order by their physician saying that they may independently take their medications, do not need anyone supervising their daily medications. They also do not need to keep a Medication Administration Record. However, the agency must have some sort of quality assurance system in place to make sure that the individual continues to self-administer medications in a safe manner.

28. Q: [.70 (a)] *How often should physicians sign phone orders? Should they be signed monthly?*

A: The Medication Administration rule tells us that phone orders should be immediately written on the individual's clinical record or telephone order form. It should be signed by the nurse who takes the order. They should be countersigned or documented by a fax prescription from the physician within ten working days. (Notice that telephone orders must be taken by an RN or LPN, NOT Authorized Direct Care Staff.)

29. Q: [.70 (a) & .70 (b) (6)] *The Master Nurse Trainer was also asked what to do if individuals who are capable of going into the community on their own purchase over the counter medication with their own money. Nurse-Trainers were told that it was okay, but if each person is not capable of self-administering, then they cannot take the meds on their own, and that a doctor's order for whatever was purchased should be obtained. Nurse-Trainers were also told to confiscate what they purchased if they do not meet the criteria for self-administration of medication. The Mental Health Code indicates individuals can use their own money and that agencies cannot take away personal property unless it is harmful. As you can see there is a conflict in information presented with current Rules and Codes that will require clarification. This information has resulted in the confiscation of items such as Aspirin, Carmex, Medicated Food Powders, Medicated Cough Drops, Sinus and Cold Medications, and the content of First Aid Kits (Neosporin Ointment, Alcohol Swabs and Peroxide), etc. Some individuals in programming feel that their rights are being abused and Nurse-Trainers believe that they are doing what is being required of them; and the Nurse-Trainers have also been told that if they do not do this, their Nurses License can be taken away from them. Should the definition of "medication" in Rule 116 be revised to exclude over-the-counter drugs? Or could there be a separate section to address over-the-counter drugs?*

A: A medication being available over-the-counter does not make it any less of a medication. Many of the common items, such as aspirin, or sinus and cold medications, can be very detrimental to a person's well-being, whether taken alone or in combination with other medications prescribed by their physician. Most over-the-counter medications are labeled with a variety of warnings related to this. Medication monitoring, as part of the nurse's assessment of an individual's health status is clearly stated in Rule 116: Individual Health Supports and Assessment (Section 116.90). Additionally, nurses do have a legal obligation to carry out physician orders. Please refer to Rule 115: Standards and Licensure Requirement for Community-Integrated Living Arrangements (Section 115.240) which states that:

"When medical services and/or medications are provided, or their administration is supervised, by employees of the licensed agency, the licensed agency shall certify that they are provided or their administration is supervised in accordance with the Medical Practice Act of 1987 and the Nursing and Advanced Practice Nursing Act. A physician shall be responsible for the medical services provided to individuals, and the management of individuals' medications."

The Department expects that the above physician and nursing duties, as part of the Community Support Team activities, will be accomplished respectfully with the highest regard for the welfare of all persons involved, both staff and individuals.

30. Q: [.70 (c)] *The Rule states that the RN retains “professional accountability” if there is a medication error. This could give the authorized staff the impression that it does not matter if they make a medication error, because the RN will be responsible for their actions.*
- A: Authorized staff are responsible for performing their own job duties appropriately. Some Nurse-Trainers may feel comfortable delegating and supervising non-licensed staff from a distance. Not all RN's will want to do this. If the RN does not feel comfortable with the ability of staff to perform their duties, there may be a need for more training. Otherwise, arrangements must be made for more RN coverage.
31. Q: [.70 (c)] *Can I lose my nursing license if someone makes a mistake?*
- A: Your license is in less jeopardy now than prior to the passage of this rule. You are in jeopardy of losing your license if you do not complete and document completion of the required elements of the rule, such as verifying completion of the 8-hour training by an RN nurse-trainer, CBTA's, on-going training, supervision of authorized staff performance, re-evaluation of staff annually and as needed, etc.
32. Q: [.70 (c)] *Why is there such an emphasis on medication error reporting?*
- A: When HCFA was here 2 years ago, one of the areas of concern was the lack of the state's ability to track errors in the waiver program. There simply was no accountability for medication issues in the community-based waiver programs. This is an area of great concern and is addressed in the rule. Currently, we are also looking at the data to be sure that training is effective and how and what needs to be changed. Lack of error reporting will not keep quality assurance from your door. It may, in fact, draw them to your door. It is not designed to “get anyone”, it is designed to ensure the safety of all the individuals in the community-based programs.
33. Q: [.70 (d)] *What med errors need to be reported and what is the procedure?*
- A: The answer to this question was modified. Memo dated 5/25/02 to Executive Directors, Community Developmental Disabilities Service Agencies, regarding Quality Assurance, Injury and Medication Error Reporting: “Effective 7/1/02 – 1) Only medication errors involving adverse outcomes will need to be faxed to ODD on a daily basis within 7 days of the errors. Effective with the FY03 Service Agreements on July 1, 2002, Quality Assurance activity reports should be submitted to Bureau of Quality Assurance and System Improvement (BQASI) on a quarterly basis by CILA agencies and semi-annually by agencies providing only DT services.
34. Q: [.80 (a)] *At the last meeting, Wendie Medina was compiling a list of all controlled medications that had to be double locked. We can find no reference to a double lock requirement in Rule 116 and have not yet received any such list; we also need to make sure that if required that only meds that truly need to be double locked are on this list.*
- A: There is reference to only locking all medication in Rule 116, controlled substances are not singled out. There is, however, specific reference to the “shift count” of all controlled substances. That is any drug or other substance listed pursuant to a schedule in the Illinois Controlled Substances Act. In addition, both physicians and pharmacists are aware of schedule medications and should indicate that on the filled prescription.
35. Q: [.80 (d)] *Nurse-Trainers were told in the last meeting that even nurses cannot repackage meds. This severely limits the types of activities and events that individuals can attend. Sending med cards home with individuals on home visits causes many concerns. Sometimes the med cards don't come back to the residential site and when this happens, the individual has to pay for replacement meds or wait until the next month to get them, as DPA will only pay for the meds one time. In addition, if the individual returns to the home without meds, medication errors may increase as they may be given late by the time the replacement meds are received from the pharmacy. Also, taking med cards on community outings draws attention and*

increases the stigma for persons with disabilities; we want to assure health and safety and encourage integration and independence, not dependence and negative attention in the community.

- A: The Illinois Nursing and Advanced Practice Nursing Act authorize nurses to administer medications, not dispense. Repackaging medications is considered dispensing. According to the Pharmacy Practices Act, dispensing can only be legally done by a pharmacist or physician. You do raise many valid concerns around the repackaging issue. Please refer the issues of home visits and outings packaging to your pharmacy, who may be able to assist you in meeting your goals of error prevention and community integration.