

**ILLINOIS DEPARTMENT OF HUMAN SERVICES
 DIVISION OF DEVELOPMENTAL DISABILITIES
 BUREAU OF CLINICAL SERVICES
 ONSITE RULE 116 REVIEW**

DATE OF REVIEW: ___/___/___ through ___/___/___

BCS REVIEWERS: _____, Quality Review Nurse Specialist

PROVIDER AGENCY: _____
 AGENCY DIRECTOR: _____
 AGENCY CONTACT: _____
 AGENCY RN-TRAINER: _____

PHONE#: (___ / ___ - _____)
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PHONE#: (___ / ___ - _____)
 Email: _____
 Email: _____
 Email: _____

CILA SITE REVIEWED: _____

PHONE#: (___ / ___ - _____)

INDIVIDUALS REVIEWED: (INDIVIDUAL# _____)
 (INDIVIDUAL# _____)

(INDIVIDUAL# _____)
 (INDIVIDUAL# _____)

(INDIVIDUAL# _____)
 (INDIVIDUAL# _____)

ADSP STAFF REVIEWED: (ADSP# _____)
 (ADSP# _____)

(ADSP# _____)
 (ADSP# _____)

Revised 8/16/17

**ILLINOIS DEPARTMENT OF HUMAN SERVICES
DIVISION OF DEVELOPMENTAL DISABILITIES
BUREAU OF CLINICAL SERVICES
RULE 116 REVIEW REPORT**

Agency Name: _____

STAFF TRAINING

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
1.	MET NOT MET	N/A	The agency registered professional nurse has met the required criteria to be approved as an RN-Trainer. Currently licensed as a registered professional nurse or advanced practice nurse in Illinois. Nurse Trainer certification signed by the DDD Medical Director. May have conditional status approval 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.	116.30b) and c) and d)
2.	MET NOT MET	N/A	Non-licensed direct care staff authorized to administer medication (ADSP) meet the requirement of being a high school graduate or equivalency (GED) and 18 years or older.	116.40c)1)2)
3.	MET NOT MET	N/A	Non-licensed direct care staff authorized to administer medication (ADSP) meet the requirement of demonstrating functional literacy. (At least 8 th grade reading level-TABE, ABLE, CASA testing)	116.40c)3)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
4.	MET	NOT MET	N/A	Non-licensed direct care staff authorized to administer medication (ADSP) meet the requirement of satisfactorily completing all Basic Health and Safety components of the DSP Core Training Program or a DHS/DDDD approved equivalent Developmental Disabilities Aide Training Program prior to the beginning of medication administration training.	116.40c)4)
5.	MET	NOT MET	N/A	Non-licensed direct care staff authorized to administer medication (ADSP) meet the requirement of being initially trained and evaluated by a Nurse-Trainer in a competency-based standardized medication curriculum specified by DHS. (8 hour med class)	116.40c)5)
6.	MET	NOT MET	N/A	Non-licensed staff authorized to administer medication (ADSP) have scored 80% or above on the written portion of the comprehensive examination furnished by DHS.	116.40c)6)

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
7.	MET NOT MET	N/A Non-licensed direct care staff authorized to administer medication (ADSP) meet the requirement of scoring 100% on a required competency-based training assessment and evaluation performed by the Nurse Trainer specific to those medications that staff is responsible to administer and which is documented on a CBTA form.	116.40c)7) 116.40d 1)-6)	
8.	MET NOT MET	NA If applicable, there is documentation that ADSP staff have successfully completed a DHS approved advanced training program specific to diabetes and insulin administration. The ADSP must be authorized and competent in medication administration for at least 6 months before beginning advanced training. Advanced training of 4 hours length is inclusive of classroom curriculum, test administration and competency based training which includes blood glucose monitoring and insulin administration via pen. The ADSP must pass the insulin related advanced training test with a minimum score of 80%. Is not a part of the original 8 hour medication administration class.	116.40e)	
9.	MET NOT MET	NA If applicable, there is documentation the authorized staff has successfully completed a DHS approved advanced training program specific to enteral tubes, their maintenance and medication administration.	116.40g)	

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
10.	MET	NOT MET	NA	The authorized DSP is certified in CPR and First Aid as required. American Red Cross or American Heart Association training accepted.	DHS/DD/CSA/ ATTACHMENT A
11.	MET	NOT MET	NA	If applicable, staff has received training in administering epinephrine by auto-injector as prescribed by a physician. Staff has been trained to summon Emergency Medical Service immediately after the use of an epinephrine auto-injector. The administration of epinephrine by auto-injector by staff is not the responsibility of the Nurse-Trainer. Agency is responsible for the training of all staff. Training can be obtained through American Red Cross, American Heart Association or American Safety and Health Institute or from a registered professional nurse or licensed practical nurse as delegated by a RN or physician. Confirm there are 2 unexpired epinephrine auto- injectors in close proximity to the individual at all times which are available for immediate use.	116.40(f)1
12.	MET	NOT MET	NA	The ADSP staff has received specific additional competency-based training and assessment by a Nurse Trainer, as deemed necessary by the Nurse Trainer, whenever a change of medication, including dosage, time and route, occurs or a new individual who requires medication enters the program.	116.40(i)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
13.	MET	NOT MET	N/A	116.40h)	
14.	MET	NOT MET	N/A	116.40m)	

INDIVIDUAL HEALTH SUPPORTS/ASSESSMENTS

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
15.	MET NOT MET	N/A The Nurse-Trainer completed an assessment of each individual PRIOR to training non-licensed staff. *The Nurse-Trainer completing the assessment must sign and date the assessment. *If the Nurse Trainer is not the registered nurse who completed the assessment, there must be evidence that the Nurse Trainer has reviewed the individual's current assessment within the last 365 day before doing any training or providing direction about medication administration to that individual.	116.40b) 1-2) A HRST does not meet Rule 116 nursing assessment requirements.	
16.	MET NOT MET	NA The nursing assessment includes an evaluation of the individual's physical status, mental status, and medical history and medication orders.	116.40b)	
17.	MET NOT MET	N/A The registered professional nurse/Nurse Trainer has assessed an individual's health status at least annually or more frequently at the discretion of the registered professional nurse.	116.90a)	
18.	MET NOT MET	NA A physician, advanced practice nurse or physician assistant has assessed each individual's health status at least annually. (May allow 395 days between assessments due to Medicare/Medicaid restrictions.)	116.90)b)	

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
19.	MET	NOT MET	N/A	The Nurse-Trainer has assessed each individual's capabilities of self-administering medication using the DHS required standardized screening and assessment instrument- the Self Administration of Medication Assessment (SAMA).	116.60a)2) 115.240)f)
20.	MET	NOT MET	N/A	The Nurse-Trainer has evaluated the individuals' ability to self-administer medications using the SAMA assessment tool at least annually. Check for frequency of the assessment.	116.60a)2) 115.240)f)
21.	MET	NOT MET	N/A	The SAMA has been signed by the Nurse-Trainer.	116.60a)2)
22.	MET	NOT MET	NA	If results of the screening and assessment (SAMA) indicate an individual is not independent with medication administration, the provider team in consultation with the Nurse-Trainer has developed a self-medication training program which is included in the Implementation Strategy/ISP.	116.60a)3)
23.	MET	NOT MET	N/A	The Nurse-Trainer is a member of the provider team and has contributed to the Implementation Strategy/ISP regarding medication self-administration skills and related medical issues and services and supports needed to assist the individual in pursuing outcomes outlined in the Person Centered Plan; if applicable. The ISP/Implementation Strategy addresses issues pertinent to the health, safety and welfare of the individual.	

MEDICATION ADMINISTRATION RECORD/ADMINISTRATION OF MEDICATION

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
24.	MET NOT MET	N/A All medications listed on the Medication Administration Record (MAR) are consistent with prescribed orders. All medications listed on the MAR are being given upon a written order of a physician, advanced practice nurse, or physician assistant. All orders have been followed as prescribed. (Does not mean "blanks" on the MAR- that issue is addressed elsewhere.) Telephone orders are taken by the RN or LPN and have been countersigned within 10 working days.	116.70a)	
25.	MET NOT MET	N/A A MAR for the current month for each individual receiving medication is kept with the medications or in the individual's clinical record.	116.70b)3)	
26.	MET NOT MET	N/A Each MAR documents the individual's name.	116.70b)1)A)	
27.	MET NOT MET	N/A Each MAR documents the name and dosage form of each medication prescribed.	116.70b)1)B)	
28.	MET NOT MET	N/A Each MAR documents the name of the prescribing physician, physician assistant, dentist, podiatrist, or certified optometrist.	116.70b)1)C)	
29.	MET NOT MET	N/A Each MAR documents the dose or quantity to be taken of each medication ordered.	116.70b)1)D)	

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
30.	MET	N/A	Each MAR documents the frequency or times of administration for each medication prescribed.	116.70b)1)(E)
31.	MET	N/A	Each MAR documents the route of administration for each medication prescribed.	116.70b)1)(F)
32.	MET	N/A	Each MAR documents the date and time of administration for each prescribed medication.	116.70b)1)(G)
33.	MET	N/A	Each MAR documents the most recent date of the order of each medication.	116.70b)1)(H)
34.	MET	N/A	Each MAR documents allergies to medications.	116.70b)1)(I)
35.	MET	N/A	The MAR documents other special considerations including special directions for preparation and administration; contraindications. Examples such as parameters for contacting nursing related to vital sign or blood sugar monitoring or other special instructions for medication preparation such as amount of liquid or shake well, etc.	116.70b)1)(J)
36.	MET	N/A	PRN medication orders indicate the condition for which the medication may be given.	116.70b)2)(A)

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
37.	MET	NOT MET	N/A	PRN medication orders include a maximum or stop dosage.
38.	MET	NOT MET	N/A	PRN medication is not used for behavioral intervention.
39.	MET	NOT MET	N/A	PRN medications are available to be administered within one hour after need is identified.
40.	MET	NOT MET	N/A	If sliding scale insulin is ordered, there is documentation that ADSP staff has consulted with the Nurse-Trainer before administering any insulin dosage determined by a blood glucose test. (ADSP staff is not allowed to calculate the insulin dosage when the dose is dependent upon a blood glucose test. ADSP staff may not administer insulin to individuals who require blood glucose monitoring greater than 3 times daily unless directed to do so by Nurse-Trainer.) It is the responsibility of the Nurse-Trainer to document instructions given to the ADSP staff.
41.	MET	NOT MET	N/A	With the exception of subcutaneous insulin administered by insulin pen and emergency epinephrine administration by auto-injector, all other medication in injectable form is administered by licensed staff.

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
42.	MET	NOT MET	N/A	Only medications regularly available without a prescription at a commercial pharmacy have been purchased for stock; may be prescribed as PRN or regularly scheduled. Orders for use as prescribed by a physician or any other person licensed to prescribe medications are on the MAR.	116.50c) and d)
43.	MET	NOT MET	N/A	Each MAR has a section that contains the full signature and title of each individual who initials the MAR.	116.70 4)
44.	MET	NOT MET	N/A	Each MAR has been completed and initialed by licensed or ADSP staff for every medication administered for each individual.	116.704)
45.	MET	NOT MET	N/A	Follow up documentation of effectiveness is present for PRN medication use.	116.40d)2)
46.	MET	NOT MET	N/A	Refusal of medication by an individual is properly documented. The refusal is noted on the MAR. ADSP staff has documented in the individual's record the reason for the refusal. The Nurse-Trainer or registered professional nurse or person licensed to prescribe medication has been contacted to receive directions or further action.	116.70 6)
47.	MET	NOT MET	N/A	Changes in medication have been correctly noted on the MAR by a licensed practical nurse, registered professional nurse, advanced practice nurse, pharmacist, physician or physician assistant, dentist, podiatrist or optometrist and reported to the Nurse-Trainer prior to the next dose.	116.70 5)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
48.	MET	NOT MET	N/A	Medication changes on the MAR are signed and dated by the licensed staff that made the changes.	116.70 5)
49.	MET	NOT MET	N/A	ADSP staff upon the direct instruction of a Nurse-Trainer may indicate on the MAR: discontinuation of a medication; change in medication schedule or apply a medication information label issued with medication by the pharmacy. The ADSP staff that completed any of the above should initial and date the changes or additions they made to the MAR. Documentation by the Nurse-Trainer is expected to confirm the instructions given to the ADSP who completed the changes.	116.70 5) A-C)
50.	MET	NOT MET	N/A	An inventory and record of use of controlled substances (medications) is maintained by registered professional nurse/Nurse Trainer. Each controlled substance shall require a separate sheet (CSCS).	116.70e)
51.	MET	NOT MET	N/A	Each CSCS indicates the name of the individual.	116.70e)1)
52.	MET	NOT MET	N/A	Each CSCS documents the name of the physician, advanced practice nurse or physician's assistant who prescribed the controlled medication.	116.70e)2)
53.	MET	NOT MET	N/A	Each CSCS documents the prescription number of the medication.	116.70e)3)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
54.	MET	NOT MET	N/A	Each CSCS documents the name and strength of the medication.	116.70e)4)
55.	MET	NOT MET	N/A	Each CSCS documents the amount of the medication given.	116.70e)5)
56.	MET	NOT MET	N/A	Each CSCS documents the amount of medication remaining after each administration.	116.70e)6)
57.	MET	NOT MET	N/A	Each CSCS documents the date and time of every controlled medication's administration.	116.70e)7)
58.	MET	NOT MET	N/A	Each CSCS documents the name of the staff who administered the medication.	116.70e)8)
59.	MET	NOT MET	N/A	Confirm each CSCS documents an accurate shift count done by authorized or licensed staff for every drug. Shift count must be completed when responsibility for administering medications changes from one ADSP or nurse to another ADSP or nurse. The ADSP or nurse passing on responsibility for medication administration has counted the controlled substances with the ADSP staff or nurse assuming responsibility for medication administration. The count completed when the controlled medication is administered is not considered a shift count.	116.70e)9)A-C)
60.	MET	NOT MET	N/A	Discrepancies in the controlled substance count have been reported to the Nurse-Trainer for review and action in accordance with agency written policy.	116.70e)9)

OBSERVATION

		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
FINDINGS				
61.	MET	N/A	116.60a)3)	
	NOT MET			
<p>Each individual's medication administration training program is being implemented as written. If applicable, the ADSP followed each individual's medication training program accurately, and documented progress accordingly.</p>				
62.	MET	N/A	116.40d) 1)	
	NOT MET			
<p>The ADSP demonstrates competency related to the rights of individuals, legal and ethical responsibilities, agency procedures, and communication pertaining to medication administration. The ADSP ensures the medication area is clean and private. The ADSP obtains medication from a locked compartment. The MAR is kept with the medications. The ADSP immediately documents the medication administration on the MAR following each administration. If administered, controlled medications have been documented and counted correctly. If administered during observation, PRN medications have been documented correctly (reason for use, time of administration).</p>				
63.	MET	N/A	116.40d) 2)	
	NOT MET			
<p>The ADSP demonstrates competency related to best practice medication administration nursing techniques. The ADSP assembles needed equipment in advance. The ADSP focuses on preparing and administering medications regardless of distractions and/or interruptions. The ADSP checks the medication with the MAR before removal; administration; returning and securing the medication. The ADSP discards used equipment, handles bio-hazard waste appropriately, secures medication in locked compartment, and leaves the medication area clean.</p>				

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
64.	MET NOT MET	N/A	116.40d) 3-5)	
		<p>The ADSP demonstrates competency related to: classes of drugs, their purpose and side effects; information regarding individuals and their medications; and techniques to check evaluate report and record vital signs when necessary.</p> <p>The ADSP reviews the MAR for allergies and/or changes before preparing medication for administration.</p> <p>The ADSP identifies each individual and matches the name/face with the name/picture on the MAR.</p> <p>The ADSP follows special directions and specific parameters for the medications to be administered and checks vitals when indicated.</p> <p>The ADSP shakes/mixes liquid medication or powders with appropriate fluids and/or foods.</p> <p>The ADSP selects correct medication, dosage, date, time, route and consistency when administering medication.</p> <p>The ADSP assists the individual as needed.</p> <p>The ADSP observes the individual to insure medication has been consumed and monitors for reactions.</p> <p>Information concerning medication side effects is available.</p>		
65.	MET NOT MET	N/A	116.50g)	
		<p>There is an RN, Advanced Practice Nurse, physician or physician assistant on duty or on call at all times.</p> <p>The ADSP can explain how to get a hold of the Nurse-Trainer for medical (including medication) concerns.</p> <p>The ADSP can explain the provider agency's protocol concerning medical (including medication) calls.</p>		
66.	Met NOT MET	NA	116.40)a)	
		<p>Medical calls are not screened by non-licensed staff.</p>		

STORAGE & DISPOSAL

		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
FINDINGS					
67.	MET	NOT MET	N/A	All medications are stored in locked compartments or within a locked medicine container, cabinet or closet.	116.80a)
68.	MET	NOT MET	N/A	Access to medications is limited to licensed personnel or authorized direct care staff.	116.80b)
69.	MET	NOT MET	N/A	Each residential program maintains an up-to-date list of employees who are authorized to administer medications.	116.80b)
70.	MET	NOT MET	N/A	The names on the list cross-reference with the signatures and initials noted in the MAR.	116.80b)
71.	MET	NOT MET	N/A	<p>All medications, including over the counter medications, are stored in their original containers with original label intact.</p> <p>Over the counter medications do not have any labeling other than the original container labeling. This labeling cannot be obscured in any way.</p> <p>No repackaging of medications.</p> <p>There is communication/policy concerning use of regularly prescribed stock medications during an individual's absence from the residence during a medication administration period.</p>	116.80d) 116.50c)1)-5)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
72.	MET	NOT MET	N/A	All prescribed medications, including over the counter medications do not have an expired expiration date.	116.40.d)2)
73.	MET	NOT MET	N/A	Medications of different consistencies/routes are stored separately.	116.40d)1)
74.	MET	NOT MET	N/A	The prescribed medication is labeled with the same information as would appear on a pharmacy label consistent with the MAR and physician's orders. Does each medication label include the name and address of the pharmacy where the prescription is sold or dispensed?	116.80e) 116.80e)1)
75.	MET	NOT MET	N/A	Each medication label includes the name or initials of the person authorized to practice pharmacy.	116.80e)2)
76.	MET	NOT MET	N/A	Each medication label includes the date the prescription was filled.	116.80e)3)
77.	MET	NOT MET	N/A	Each medication label includes the name of the person for whom it was prescribed.	116.80e)4)
78.	MET	NOT MET	N/A	Each medication label includes the prescription number of the prescription.	116.80e)5)

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
79.	MET	NOT MET	N/A	Each medication label includes the last name of the practitioner who prescribed the prescription.	116.80e)6)
80.	MET	NOT MET	N/A	Each medication label includes the directions for use as contained in the prescription.	116.80e)7)
81.	MET	NOT MET	N/A	Each medication label includes the proprietary name or established name of the drug, the dosage, and the quantity.	116.80e)8)
82.	MET	NOT MET	N/A	The agency disposes of all medications in accordance with Federal and State laws. The ADSP knows the agency's protocol or procedure for disposing of medications.	116.80f)

MEDICATION SELF-ADMINISTRATION

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
83.	MET NOT MET	N/A	116.60(c) 1-6)	
		<p>The individual demonstrates he/she has successfully achieved the minimal training requirements to be considered capable of safely self-administering his/her own medications.</p> <p>The individual can identify medication by any of the following methods: name, purpose, size, shape, color or other distinguishing feature.</p> <p>The individual knows dose or quantity to be taken.</p> <p>The individual knows route of administration.</p> <p>The individual knows frequency of times of administration.</p> <p>The individual knows purpose of medication, special instructions, common side effects and potential consequences of not taking the medication properly.</p> <p>The individual knows when to seek medical assistance.</p>		
84.	MET NOT MET	N/A	116.60(b)1) 116.60(a)2)	
		The individual has been determined to be competent to self-administer medications by a registered nurse or advanced practice nurse. (SAMA)		
85.	MET NOT MET	N/A	116.60(b)2)	
		The individual has been approved to self-administer medications by the provider team.		
86.	MET NOT MET	N/A	116.60(b)3)	
		The individual has been authorized to self-administer medications by a written order of a physician.		

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
87.	<p>MET</p> <p>NOT MET</p> <p>N/A</p>	116.60e)	
88.	<p>MET</p> <p>NOT MET</p> <p>N/A</p>	116.60f) 116.80c)	
89.	<p>MET</p> <p>NOT MET</p> <p>N/A</p>	116.70b)7 116.60g)	

QUALITY ASSURANCE/NURSE TRAINER OVERSIGHT OF PROGRAM

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
90.	MET NOT MET	N/A	The Nurse Trainer has routinely assessed and evaluated the outcomes of delegated tasks and general nursing care for individuals receiving services? The RN has assessed the general nursing care for individuals receiving services.	116.20 Delegation/Supervision Use worksheets. Question training, instructions on caring for individuals with medical conditions.	
91.	MET NOT MET	N/A	The Nurse Trainer has ensured all prescribed medications are administered to individuals in accordance with the Mental Health and Developmental Disabilities Administrative Act and the Illinois Nursing and Advanced Practice Nursing Act. Medications are individualized and based on a diagnosed clinical condition.	116.50a)	
92.	MET NOT MET	N/A	Is there a medication error report for every medication error noted? (A medication error is defined as administration of medication other than as prescribed- wrong medication being given, medication being given at the wrong time, in the wrong dose, via the wrong route or by the wrong person or omitted entirely. A lack of documentation or any error in documentation is also a medication error.) Refusal of medication is not an error per Rule 116.	116.70c) 116.20	
93.	MET NOT MET	N/A	Medication errors have been reported to the registered professional nurse or Nurse Trainer immediately and the report completed within 8 hours or before the end of the shift in which the error was discovered.	116.70c)	
94.	MET NOT MET	N/A	The Nurse Trainer conducts a review of medication errors within 7 days of occurrence to monitor and recommend corrective action.	116.70c)	
95.	MET NOT MET	N/A	At least annually the agency, including the Nurse Trainer, has summarized and analyzed all medication errors to identify patterns and trends and establish corrective action.	116.100c)	

FINDINGS		RULE 116 REVIEW STANDARDS		REQUIREMENT	REVIEWER NOTES/EXAMPLES
96.	MET	NOT MET	N/A	116.70d)	
97.	MET	NOT MET	N/A	116.70d)	
98.	MET	NOT MET	N/A	ADD Waiver Appendix G-3 ii Children's Residential Waiver Appendix G-3 C iii	
99.	MET	NOT MET	N/A	116.100a 1), 2) and 3)	

**ILLINOIS DEPARTMENT OF HUMAN SERVICES
DIVISION OF DEVELOPMENTAL DISABILITIES
BUREAU OF CLINICAL SERVICES
RULE 116 REVIEW MODULE REPORT DOCUMENT**

Agency Name: _____

POLICIES & PROCEDURES

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
100.	<p>MET</p> <p>N/A</p> <p>NOT MET</p>	<p>Has the agency developed written policies and procedures governing the supervision and monitoring of Authorized Direct Support Personnel (ADSP)?</p> <ol style="list-style-type: none"> Verify the policy and procedure includes a provision addressing the required qualifications of the Nurse-Trainer. Verify the policies and procedures state that only a Nurse-Trainer may delegate and supervise the task of medication administration. Verify the policies and procedures includes a provision addressing the requirement that prior to training non-licensed staff to administer medication, each RN-trainer shall perform: <ol style="list-style-type: none"> An assessment of each individual's medical history, including a physical and mental status exam. An evaluation of each individual's medication orders and prescribed medications. Agency has a policy to explain their procedure which provides "clear evidence" that every Nurse Trainer has reviewed an individual's current assessment within the last 365 days before doing any training or providing direction about medication administration for that individual. Verify the policy and procedure includes provisions for the transfer of responsibility of selected tasks which do not require nursing judgments or include the performance of nursing duties. Verify the policy and procedure defines supervision as an active process, in which the registered professional nurse monitors, directs, guides, and evaluates the outcomes of a delegated task. Verify the policy and procedure specify the registered professional nurse maintains the accountability for the tasks and responsibilities, as subcomponents of total patient care, delegated to 	<p>116.110a) 1)</p> <ol style="list-style-type: none"> 116.30b&-c) 116.40a) 116.40b) 116.40b) 1) and 2) 116.20 (Delegation) 116.20 (Delegation) (Supervision) 116.20 (Delegation) 	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>authorized direct care staff.</p> <p>8. Verify the policy and procedure includes a provision that stipulates a registered professional nurse, Nurse -Trainer, advanced practice nurse, physician, or physician assistant shall be on duty or on call at all times in any program covered by this part.</p>	<p>8. 116.50g)</p>	
101.	<p>Has the Provider developed written policies and procedures governing the training of ADSP employees?</p> <p>1. Verify the policy and procedure specifies all ADSP staff shall meet required criteria prior to authorization including:</p> <ul style="list-style-type: none"> a. Verification the ADSP is age 18. b. Verification the ADSP has completed high school or its equivalency (GED). c. Verification the ADSP is functionally literate. d. Verification the ADSP has satisfactorily completed all components of the DSP Basic Health and Safety, or a DHS/DDD approved equivalent. e. Has been initially trained and evaluated by a Nurse-Trainer in a competency-based standardized medication curriculum specified by DHS. f. Verification the ADSP has successfully passed the required DHS comprehensive examination with a minimum score of 80%. g. Verification the ADSP has scored 100% on a required competency-based training assessment (CBTA) specifically pertinent to those medications that staffs are responsible to administer as evaluated by the Nurse-Trainer. <p>2. Verify the policy and procedure also includes verification the ADSP has current certification in CPR and First Aid.</p> <p>3. Verify the policy and procedure also includes verification the ADSP has current EpiPen certification (if applicable).</p> <p>4. The policy and procedure should specify how training on Epi-Pen use will be obtained. Policy should specify that two unexpired epinephrine auto-injectors should be in close proximity to the individual at all times(either within arm's</p>	<p>116.110b) 6)</p> <p>1. 116.40c) 1-7)</p> <p>2. DHS/DD/CSA / Attachment A)</p> <p>3. 116.40f)1)</p> <p>4. 116.40f)1-2)</p> <p>(Review procedure on EpiPens.)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>reach of the individual responsible for administering when away from the residence or in a known easily accessible location when at the residence.)</p> <p>5. The policy/procedure should state that Emergency medical services must be summoned immediately after the Epi-Pen use.</p> <p>6. The agency has a policy and procedure concerning the training and authorizing of direct care staff to administer medications through enteral tubes. The agency has a policy concerning the DHS approved advanced training program which ADSP staff must successfully complete.</p>	<p>5. 116.40(f)3</p> <p>6. 116.40g</p> <p>(Review procedure on administering medications via enteral tubes.)</p>	
102.	<p>Has the provider developed written policies and procedures governing the use of subcutaneously administered insulin via pre-filled pen by the ADSP staff?</p> <p>1. Policy should state that ADSP must successfully complete a DHS approved 4 hour advanced training program specific to diabetes and insulin administration.</p> <p>2. The policy must state that ADSP staff must consult with the Nurse-Trainer before administering any subcutaneous insulin dose determined by a blood glucose test. ADSP staff may not calculate the insulin dosage needed when the dose is dependent upon a blood glucose test report.</p>	<p>116.110b)2)</p> <p>1. 116.40e)</p> <p>2. 116.40e)1)&2)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>3. The policy and procedures should explain how communication between the Nurse-Trainer and ADSP staff regarding reporting of blood glucose results by the ADSP and dosage instructions given by the Nurse-Trainer to the ADSP staff will be documented. The Nurse-Trainer is responsible for documenting instructions given to the ADSP staff.</p>	<p>3. 116.40e) (Review procedures concerning insulin administration and how communication between Nurse-Trainer and ADSP regarding sliding scale insulin is to be documented.)</p>	
103.	<p>NOT MET</p> <p>Has the provider developed written policies and procedures governing the recording and reporting of all instances of retraining and retesting for failure to qualify as an ADSP employee?</p> <ol style="list-style-type: none"> 1. Verify the policy and procedure includes a provision addressing additional education and testing following an employee's failure to qualify as an ADSP staff following initial training and testing. 2. Verify the policy and procedure includes provisions for the revocation of a staff's authorization to administer medication. 	<p>116.110a)4) 1. 116.40j) 2. 116.40l)</p>	
104.	<p>NOT MET</p> <p>Has the Provider developed written policies and procedures governing the annual review and necessary retraining of ADSP employees in medication administration?</p> <ol style="list-style-type: none"> 1. Verify the policies and procedures include provisions for annual review of ADSP in theory and practice. 2. Verify the policies and procedures include provisions for necessary individual specific retraining of ADSP by the Nurse-Trainer whenever a change of medication occurs or a new individual enters the residential program. 	<p>116.110a) 2) 1. 116.40h) 2. 116.40i)</p>	

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
105.	MET NOT MET	Has the provider developed written policies and procedures governing the training, review and necessary retraining of ADSP employees addressing the required documentation and maintenance of personnel and training files? 1. Verify the policies and procedures include a provision stating that clear documentation of training, retraining, and evaluation shall be kept in each staff or contractual person's personnel file by each provider where ADSP are employed.	116.110b)6) 1. 116.40m)	
106.	MET NOT MET	Has the Provider developed written policies and procedures, consistent with rules, regulations, federal and State law, governing the assessment of the individual's health status? 1. Verify the policies and procedures include provisions for an annual assessment of the individual's health status by the RN. 2. Verify the policies and procedures include provisions for the annual assessment of each individual's ability to self-medicate with the Self Administration of Medication Assessment (SAMA) tool.	116.110c) 1. 116.90a) 2. 116.60a)2)	
107.	MET NOT MET	Has the Provider developed written policies and procedures governing medication administration stating that other than subcutaneous insulin in pre-filled pen form and emergency epinephrine in auto-inject form all other injections must be administered by licensed staff?	116.110b)2) 116.50b)	
108.	MET NOT MET	Has the Provider developed written policies and procedures governing the distribution of medications, including controlled substances, and persons authorized to distribute medications? 1. Verify the policy and procedure specifies all medication shall be given only upon the written order of a physician, advanced practice nurse, or physician assistant. 2. Verify the policy and procedure includes the provision that only licensed medical staff can take and sign off on a telephone order. 3. Verify the policy and procedure includes the provision that all telephone orders are to be countersigned, or documented by facsimile prescription, by the physician within ten working days.	116.110b) 1) 1. 116.70a) 2. 116.70a) 3. 116.70a)	

	FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES	
109.	MET	NOT MET	N/A	<p>Has the Provider developed written policies and procedures governing the administration of medications addressing the requirement that a Medication Administration Record (MAR) be maintained for each individual who is not independent with medication administration?</p> <ol style="list-style-type: none"> 1. Verify the policy and procedure includes a provision addressing the MAR requirements. <ol style="list-style-type: none"> a. the individual's name; b. the name and dosage form of the drug; c. the name of the prescribing practitioner; d. the dose or quantity to be taken; e. frequency or times of administration; f. the route of administration; g. the date and time given; h. the most recent date of the order; i. allergies to medication; j. any special considerations, including special directions and precautions for the medication's preparation and administration; 2. The policy and procedure also includes provision that in addition to above, PRN medication orders need to include: <ol style="list-style-type: none"> a. conditions for which the medication may be given; b. maximum or stop dose. 	<p>116.110b) 2)</p> <ol style="list-style-type: none"> 1. 116.70b) 1) A-J) 2. 116.70b)2)A-B) 	
110.	MET	NOT MET	N/A	<p>Has the Provider developed written policies and procedures addressing the required documentation in the MAR as part of the administration of medications?</p> <ol style="list-style-type: none"> 1. Verify the policy and procedure includes a provision that the MAR be kept with the medications, or present when and where the medications are taken, for appropriate notation. 2. Verify the policy and procedure includes provisions that each MAR has a section which contains the full signature and title of each person who initials the MAR. 3. Verify the policy and procedure specifies the MAR shall be completed and initialed immediately after administered. 4. Verify the policy and procedure includes the provision that any changes in medication must be noted on the MAR by a licensed 	<p>116.110b) 2)</p> <ol style="list-style-type: none"> 1. 116.70b) 3) 2. 116.70b)4) 3. 116.70b)4) 4. 116.70b) 5) 	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>medical professional and reported to the Nurse-Trainer prior to the next dose.</p> <p>5. The policy and procedure includes a provision that upon the direct instructions of the Nurse-Trainer an ADSP may indicate of the MAR the following actions:</p> <ol style="list-style-type: none"> Discontinuation of a medication; Change in schedule of a medication; and/or Application of a medication information label issued with a medication by a licensed pharmacy. <p>6. The agency has a policy and procedure indicating how the communication between the Nurse-Trainer and the ADSP concerning changes to the MAR are documented.</p> <p>7. Verify the policy and procedure specifies all refusals must be noted in the MAR and reason for refusal documented in the individual's record. Policy and procedure should indicate that ADSP staff is to notify the registered professional nurse, Nurse-Trainer, or person licensed to prescribe medication in Illinois to receive direction on any action to be taken.</p> <p>8. There is a policy and procedure governing documentation of a PRN medication's effectiveness.</p>	<p>5. 116.70b)5)A-C)</p> <p>6. 116.70b)5)A-C) (Review procedure for #6.)</p> <p>7. 116.70b)6)</p> <p>8. 116.40d)2)</p>	
111.	<p>Has Provider developed written policies and procedures governing the administration of controlled substances and required documentation?</p> <p>1. Verify the policy and procedure includes a provision that the registered professional nurse shall maintain an inventory and a record of the use of controlled substances and each substance shall require a separate sheet indicating:</p> <ol style="list-style-type: none"> the name of the individual; the name of the prescriber; the prescription number; the name of the drug and strength; the amount used; the amount remaining; 	<p>116.110b) 1)</p> <p>1. 116.70e)1-9)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>g. the time and date administered;</p> <p>h. the name of the individual who administered the medication;</p> <p>i. documentation of a shift count done by the ADSP.</p> <p>2. Verify the policy and procedure states that any discrepancies shall be reported to the nurse-trainer for review and action.</p>	2. 116.70c) 9)	
112.	<p>Has the Provider developed written policies and procedures governing the storage and safekeeping of stock medications?</p> <p>1. Verify the policy and procedure specifies that only drugs regularly available without prescription at a commercial pharmacy may be purchased for stock use whether prescribed as a scheduled medication or as a PRN medication.</p> <p>2. Verify the policy and procedure states that stock medications can only be given upon the written order of a prescribing practitioner.</p> <p>3. Verify the policy and procedure states stock medications are administered from the original container and the prescription instructions as written by the physician or any other person licensed to prescribe medications in Illinois and as interpreted by the Nurse-Trainer, will be placed on the MAR and followed as written.</p> <p>4. Policy and procedure should address requirement that PRN medications be administered within one hour after the need is identified.</p> <p>5. The agency has a policy and procedure to address how the use of regularly prescribed stock medications during an individual's absence from the residence during a medication administration period will be handled.</p>	<p>116.110b) 4)</p> <p>1. 116.50c)</p> <p>2. 116.50c)</p> <p>3. 116.50c)3)</p> <p>4. 116.50f)</p> <p>5. 116.50c)5) (Review procedure related to #5.)</p>	
113.	<p>Has the Provider developed written policies and procedures governing of the storage and safekeeping of medications which addresses the labeling of each medication?</p> <p>1. Verify the policy and procedure includes a provision that all medications are to be stored in their original containers.</p> <p>2. Verify the policy and procedure includes all prescription medications must have a label with the same information as would appear on a pharmacy label to show;</p> <p>a. the pharmacy name and address where the prescription is dispensed;</p> <p>b. the name/initials of the person authorized to practice pharmacy;</p>	<p>116.110b) 4)</p> <p>1. 116.80d)</p> <p>2. 116.80e)1-8)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>c. the date on which the prescription was filled;</p> <p>d. the name of the patient;</p> <p>e. the prescription number as filed in the prescription files;</p> <p>f. the last name of the prescribing practitioner;</p> <p>g. the directions for use as contained in the prescription;</p> <p>h. the proprietary name or names or the established name of the drugs, the dosage, and the quantity.</p>		
114.	<p>MET</p> <p>NOT MET</p> <p>Has the Provider developed written policies and procedures governing the disposal of medications, including controlled substances?</p> <p>1. Verify the policy and procedure states that disposal of all medications is in accordance with federal and state laws.</p> <p>a. Verify the policy and procedure specifies a witness must observe and document wasting of controlled substances.</p>	<p>116.110(b) 5)</p> <p>1. 116.80f (Review procedure.)</p>	
115.	<p>MET</p> <p>NOT MET</p> <p>Has the Provider developed written policies and procedures governing the distribution of medications that addresses access to medications including controlled substances?</p> <p>1. Verify the policy and procedure includes a provision that all drugs must be stored in locked compartments or within the locked medicine container, cabinet or closet.</p> <p>2. Verify the policy and procedure specifies that access be limited to only licensed and authorized staff.</p> <p>3. Verify the policy and procedure includes an up-to-date list of ADSP staff is to be maintained.</p>	<p>116.110(b) 1)</p> <p>1. 116.80a)</p> <p>2. 116.80b)</p> <p>3. 116.80b)</p>	
116.	<p>MET</p> <p>NOT MET</p> <p>Has the Provider developed written policies and procedures governing the distribution of medications which addresses the requirements necessary to consider an individual determined to be competent to self-administer medications?</p> <p>1. Verify the policy and procedure includes demonstration that the individual has achieved the training requirements.</p> <p>a. The individual knows the name and/or can identify each medication prescribed.</p> <p>b. The individual understands the dosage and/or quantity of each medication to be taken.</p> <p>c. The individual knows the route of each medication.</p> <p>d. The individual knows the frequency or times of each</p>	<p>116.110(b) 1)</p> <p>1. 116.60(c) 1-6)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
117.	<p>medication's administration.</p> <p>e. The individual understands each medication's purpose, special instructions, side effects, and potential consequences of not taking the medication properly.</p> <p>f. The individual knows when to seek medical assistance and/or what action to take in the event of a medication error, or adverse reaction.</p> <p>Has the Provider developed written policies and procedures governing the storage and safekeeping of medications, including controlled substances, by individuals determined to be competent to self-administer their own medications?</p> <p>1. Verify the policy and procedure addresses the safeguarding of medication kept in an individual's possession.</p> <p>2. Verify the policy and procedure includes a provision for a back-up system (i.e. duplicate key, a copy of the combination, etc.) if needed for emergencies.</p>	<p>116.110b)4)</p> <p>1. 116.80c)</p> <p>2. 116.60f)</p>	
118.	<p>Has the Provider developed written policies and procedures governing the distribution of medications, including controlled substances, and persons authorized to distribute medications which address access to medications by individuals determined to be competent to self-administer their own medications?</p> <p>1. Verify the policy and procedure includes the provision that the individual has been determined to be capable by a registered professional nurse or advanced practice nurse</p> <p>2. Verify the individual's provider team has approved the self-administration of medication by the individual.</p> <p>3. Verify the policy and procedure includes the provision that there be a written order by the physician for the individual to self-administer his/her own medications.</p>	<p>116.110b)1)</p> <p>1. 116.60b)1)</p> <p>2. 116.60b) 2)</p> <p>3. 116.60b) 3)</p>	
119.	<p>Has the Provider developed written policies and procedures governing the administration of medications which addresses the assistance for individuals determined to be competent to self-administer medication, but physically impaired?</p> <p>1. Verify the policy and procedure specifies assistance is done upon the individual's request and guidance when needed.</p>	<p>116.110b)2)</p> <p>1. 116.60d)</p>	

FINDINGS		RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
120.	MET NOT MET	<p>Has the Provider developed written policies and procedures governing the development and implementation of a quality assurance system (for individuals determined to be competent to self-administer medication) to ensure that self-administered medications are taken in accordance with prescribed orders?</p> <ol style="list-style-type: none"> Verify the policy and procedure includes a provision addressing the development and implementation of a quality assurance system for individuals who independently self-administer their medications which ensures all medications are taken in accordance with prescribed orders. Verify the policy and procedure includes a provision which addresses the documentation in the clinical record of all observation and assistance by ADSP staff of each medication self-administration. 	<p>116.110b) 3)</p> <ol style="list-style-type: none"> 116.70b)7) 116.60g) (Review procedure related to the quality assurance system.) 116.60e) 	
121.	MET NOT MET	<p>Has the Provider developed written policies and procedures governing a systematic review of all adverse drug reactions to identify contributing factors and plan corrective action?</p> <ol style="list-style-type: none"> Verify the policy and procedure includes a provision for the immediate reporting of the signs and symptoms of a suspected drug reaction to the registered professional nurse. Verify the policy and procedure includes provisions for the documentation of a suspected adverse drug reaction in the individual's record and an adverse drug reaction report completed within eight hours or before the shift ends. 	<p>116.110a) 3)</p> <ol style="list-style-type: none"> 116.70d) 116.70d) 	
122.	MET NOT MET	<p>Has the Provider developed written policies and procedures governing the systematic review of all medication errors to identify contributing factors and plan corrective action?</p> <ol style="list-style-type: none"> Verify the policy and procedure includes a provision for the immediate reporting of medication errors to the registered professional nurse, Nurse-Trainer or person licensed to prescribe medication in Illinois to receive direction on any action to be taken. Verify the policy and procedure includes provisions for the documentation of medication errors in the individual's record and a medication error report completed within eight hours or before the end of the shift and sent to the Nurse-Trainer. Verify the policy and procedure includes provisions for the 	<p>116.110a) 3)</p> <ol style="list-style-type: none"> 116.70c) 116.70c) 116.70c) ADD Waiver 	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>reporting of adverse medication errors to the DHS Bureau of Quality Management (BQM) and to the Office of the Inspector General (OIG) as applicable.</p> <p>4. Verify the policy and procedure includes provisions that all medication error reports are to be maintained as a part of the provider's quality assurance program.</p>	<p>Appendix G-3 i Children's Residential Waiver Appendix G-3 c iii</p> <p>4. 116.70c)</p>	
123.	<p>Has the Provider developed written policies and procedures governing the quality assurance (QA) medication review that addresses the required review of all medication errors?</p> <p>1. Verify the policy and procedure specifies the RN-trainer will conduct a QA review of all medication errors within seven days for the purpose of recommending corrective action.</p> <p>2. Verify the policy and procedure specifies the QA reviews of all medication errors are to be included in the annual review.</p> <p>3. The analysis and corrective action arising from the annual review of medication errors must be documented and that documentation shall be retained by the agency for at least five years.</p>	<p>116.110b) 3)</p> <p>1. 116.70c)</p> <p>2. 116.100c)</p> <p>3. 116.100c)</p>	
124.	<p>Has the Provider developed written policies and procedures governing the quality assurance (QA) medication review process?</p> <p>1. Verify the policy and procedure includes a provision the QA review must be done by a registered professional nurse, advanced practice nurse, licensed practical nurse, pharmacist or physician.</p> <p>2. The policy and procedure addresses the process by which medication orders, medication labels and medications listed on the MAR are reviewed for all individuals to ensure they match physician orders; the MARs (for persons who are not self-medicating) are reviewed to ensure that they are completed appropriately for medication administered as prescribed; refusal by the individual and full signatures provided for all initials used.</p> <p>3. Verify the policy and procedure includes a provision that the medication QA review shall be done at least quarterly, but may be done more frequently at the RN-trainer's discretion.</p> <p>4. Verify the policy and procedure includes a statement regarding documentation of QA process.</p> <p>5. Verify the policy and procedure includes the provision that all medication QA records are confidential and only disclosed in</p>	<p>116.110b) 3)</p> <p>1. 116.100a)</p> <p>2. 116.100a)1-3)</p> <p>3. 116.100b)</p> <p>4. 116.100b)</p> <p>5. 116.100d)</p>	

FINDINGS	RULE 116 REVIEW STANDARDS	REQUIREMENT	REVIEWER NOTES/EXAMPLES
	<p>accordance with the provisions of Part 21 of Article VIII of the Code of Civil Procedure [735 ILCS 5/8-2105].</p>		
125.	<p>MET</p>	<p>116.110d)</p> <p>1. 116.40d)</p> <p>a. 116.40d)1)</p> <p>b. 116.40d) 2)</p> <p>c. 116.40d) 3)</p> <p>d. 116.40d)4)</p> <p>e. 116.40d)5)</p>	
	<p>NOT MET</p>		
	<p>N/A</p>		
	<p>Does each Provider have a copy of policies and procedures related to medication administration on file and available?</p> <p>1. Verify ADSP staff know how to access the medication policy, procedure and protocol information addressing:</p> <p>a. Best practice standards related to individual rights; legal and ethical responsibilities; agency procedures and communication pertaining to medication administration.</p> <p>b. Best practice techniques used with medication administration.</p> <p>c. Classes of drugs, therapeutic effects, and side effects.</p> <p>d. Specific information regarding the individuals whom the staff will administer medication to, and information regarding the medications the staff will administer.</p> <p>e. Techniques to check, evaluate, report, and record vital signs necessary for safe administration of medication.</p>		
	<p>(Review procedures for letter b-best practice techniques in medication administration-oral, topical, eye, otic, respiratory, and rectal.)</p>		

