

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL082-097	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED R-C 03/19/2025
NAME OF PROVIDER OR SUPPLIER CHANGING PATHS NC II		STREET ADDRESS, CITY, STATE, ZIP CODE 205 MARTHA LANE, UNITS 7 & 8 CLINTON, NC 28328		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	<p>INITIAL COMMENTS</p> <p>A complaint and follow up survey was completed on March 19, 2025. The complaint was substantiated (Intake #NC00227677). Deficiencies were cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment.</p> <p>This facility has a current census of 39. The survey sample consisted of audits of 4 current clients and 2 former clients.</p>	V 000		
V 105	<p>27G .0201 (A) (1-7) Governing Body Policies</p> <p>10A NCAC 27G .0201 GOVERNING BODY POLICIES</p> <p>(a) The governing body responsible for each facility or service shall develop and implement written policies for the following:</p> <p>(1) delegation of management authority for the operation of the facility and services;</p> <p>(2) criteria for admission;</p> <p>(3) criteria for discharge;</p> <p>(4) admission assessments, including:</p> <p>(A) who will perform the assessment; and</p> <p>(B) time frames for completing assessment.</p> <p>(5) client record management, including:</p> <p>(A) persons authorized to document;</p> <p>(B) transporting records;</p> <p>(C) safeguard of records against loss, tampering, defacement or use by unauthorized persons;</p> <p>(D) assurance of record accessibility to authorized users at all times; and</p> <p>(E) assurance of confidentiality of records.</p> <p>(6) screenings, which shall include:</p> <p>(A) an assessment of the individual's presenting problem or need;</p> <p>(B) an assessment of whether or not the facility</p>	V 105		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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V 105	Continued From page 1 can provide services to address the individual's needs; and (C) the disposition, including referrals and recommendations; (7) quality assurance and quality improvement activities, including: (A) composition and activities of a quality assurance and quality improvement committee; (B) written quality assurance and quality improvement plan; (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services; (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service; (E) strategies for improving client care; (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges: (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death; (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field;	V 105		

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V 105	<p>Continued From page 2</p> <p>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to adhere to its discharge policy affecting 2 of 2 former clients (FC) (#5 and #6). The findings are:</p> <p>Review on 03/18/25 of the facility policy and procedure for "Termination of Client Services" revealed: - Revised 3/2025. - "Policy: termination of client services shall occur when clinically or administratively appropriate and in a timely manner. Changing Paths NC II clinicians shall adhere to the following procedures related to termination of client services. 1. Termination of client services may occur under the following conditions:...c. More than 14 days of inactivity in treatment have occurred, arrangements have been made for sessions with this client that are less frequent than once per month, and/or the client did not respond to phone calls or a 'Missed Appointment' notification..." - "5. A Discharge Summary is to be completed after 14 days of inactivity or client failure to respond to reach-out phone call or a letter unless other arrangements have been made, including sessions with this client that are less frequent than once per month..."</p> <p>Review on 03/19/25 of a "Discharge Plan" for FC #5 revealed: - "Reason for Discharge: Unable to contact client." - Duration of program: 9/16/24 - 12/29/24. - "Client last dosed at 80 mg (milligrams)</p>	V 105		

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V 105	Continued From page 3 Methadone on 12/29/24. Multiple unsuccessful attempts were made to reach her." - Discharge date: 01/29/25. - No signature or date of completion of the discharge summary. Review on 03/19/25 of a "Discharge Plan" for FC #6 revealed: - "Reason for Discharge: Unable to contact client." - Duration of program: 9/26/24 - 02/07/25. - "Client was last dosed at 65 mg of Methadone on 2/7/25. Multiple unsuccessful attempts were made to reach him were made." - Discharge date: 03/03/25. - No signature or date of completion of the discharge summary. Interview on 03/18/25 and 03/19/25 the Facility Director/Family Nurse Practitioner stated: - The facility was behind on the completion of discharge summaries. - She had completed the discharge summaries for FC #5 and FC #6 on 03/18/25. - She would ensure discharge summaries are completed per policy time frames.	V 105			
V 113	27G .0206 Client Records 10A NCAC 27G .0206 CLIENT RECORDS (a) A client record shall be maintained for each individual admitted to the facility, which shall contain, but need not be limited to: (1) an identification face sheet which includes: (A) name (last, first, middle, maiden); (B) client record number; (C) date of birth; (D) race, gender and marital status; (E) admission date;	V 113			

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V 113	<p>Continued From page 4</p> <p>(F) discharge date; (2) documentation of mental illness, developmental disabilities or substance abuse diagnosis coded according to DSM IV; (3) documentation of the screening and assessment; (4) treatment/habilitation or service plan; (5) emergency information for each client which shall include the name, address and telephone number of the person to be contacted in case of sudden illness or accident and the name, address and telephone number of the client's preferred physician; (6) a signed statement from the client or legally responsible person granting permission to seek emergency care from a hospital or physician; (7) documentation of services provided; (8) documentation of progress toward outcomes; (9) if applicable: (A) documentation of physical disorders diagnosis according to International Classification of Diseases (ICD-9-CM); (B) medication orders; (C) orders and copies of lab tests; and (D) documentation of medication and administration errors and adverse drug reactions. (b) Each facility shall ensure that information relative to AIDS or related conditions is disclosed only in accordance with the communicable disease laws as specified in G.S. 130A-143.</p> <p>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to have a signed consent to seek</p>	V 113		

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V 113	Continued From page 5 emergency treatment from a hospital or physician for 1 of 4 audited clients (#3). The findings are: Review on 03/18/25 of client #3's record revealed: -Admission date of 11/18/24. -Diagnoses of Opioid Dependence. -No signed consent granting permission to seek emergency treatment. During interview on 03/19/25 the Program Director/Family Nurse Practitioner revealed: -She would ensure client #3 signed the consent.	V 113			
V 237	27G .3604 (A-D) Outpt. Opioid - Operations 10A NCAC 27G .3604 OPERATIONS (a) Hours. Each facility shall operate at least six days per week, 12 months per year. Daily, weekend and holiday medication dispensing hours shall be scheduled to meet the needs of the client. (b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost. (c) Compliance With DEA Regulations. Each	V 237			

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V 237	<p>Continued From page 6</p> <p>facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate.</p> <p>(d) Compliance With State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.</p> <p>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to failed to assure compliance with regulations in 42 CFR (Code of Federal Regulations) Part 8 for documentation to ensure clients attended a minimum of 2 counseling sessions per month during the first year of treatment and at least 1 counseling session in all subsequent years as documented in the treatment plan, affecting 4 of 4 audited clients (#1, #2, #3 and #4). The findings are:</p> <p>Review on 06/20/24 of SAMHSA regulations and guidelines revealed:</p>	V 237		

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V 237	<p>Continued From page 7</p> <p>- "42 CFR § 8.12(f) (5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress."</p> <p>- "Substance Abuse Counseling Appropriately trained, experienced, and certified or licensed substance abuse counselors should provide services at the intensity and for the duration required to meet each patient's needs as referenced in the individualized treatment plan."</p> <p>Finding #1: Review on 03/18/25 and 03/19/25 of client #1's record revealed: - Admission date of 08/06/24. - Diagnoses of opioid use disorder, Adjustment Disorder, Alcohol Abuse, Nicotine Dependence, Cannabis Abuse, Depression and Schizophrenia. - Order dated 02/18/25, client #1 was currently taking methadone 95 mg (milligrams) daily. - Person-Centered Plan dated 01/13/25 revealed: "Meet with counselor to identify the impact of trauma on his recovery biweekly beginning August 28, 2024." - No counseling documentation for the month of September 2024 and January 2025. Only one counseling documented case note for the months of October 2024, November 2024, December 2024 and February 2025.</p> <p>Interview on 03/18/25 client #1 stated: - He had received services for approximately 7 months. - He received 1 counseling session per month. - He could contact Counselor #1 anytime.</p>	V 237			

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V 237	<p>Continued From page 8</p> <p>Finding #2 Review on 03/18/25 and 03/19/25 of client #2's record revealed: -Admission date of 09/09/24. Diagnoses of Opioid Use Disorder, Post-Traumatic Stress Disorder, Depression, General Anxiety Disorder, Adjustment Disorder and Schizophrenia. -Order dated 01/14/25, client #2 was currently taking methadone 65mg daily. -Therapy Treatment Plan dated 09/06/24 revealed: "Therapist will employ recovery strategies and motivational interventions to assist client with achieving and maintaining sobriety during bi-weekly therapy sessions." -No counseling documentation for the month of January 2025. Only one counseling documented case note for the months of October 2024, December 2025 and February 2025.</p> <p>Interview on 03/18/25 client #2 stated: -He had received services since September 2024. -He had counseling sessions 2 times a month with Counselor #1.</p> <p>Finding #3 Review on 03/18/25 and 03/19/25 of client #3's record revealed: -Admission date of 11/18/24. -Diagnoses of Opioid Use Disorder. -Order dated 01/17/25, client #3's was currently taking methadone 110mg daily. -Therapy Treatment Plan dated 03/19/25 revealed: "...bi-weekly therapy over a period of 12 months as measured by OPT, Peer Support, Physician Assistant, Psychiatrist and other collaterals." -No counseling documentation provided.</p>	V 237		

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V 237	<p>Continued From page 9</p> <p>Interview on 03/18/25 client #3 stated: -He received services for 5 months. -He transferred from another Methadone clinic. -He saw Counselor #1 at least 2 or 3 times a month.</p> <p>Finding #4 Review on 03/18/25 and 03/19/25 of client #4's record revealed: -Admission date of 08/14/24. -Diagnoses of Opioid Use Disorder, Depression, Hypertension and Tobacco Use. -Order dated 08/14/24, client #4 was currently taking methadone 180mg daily. -Therapy Treatment Plan dated 10/30/24 revealed:"...bi-weekly therapy over a period of 12 months as measured by OPT, Peer Support, Physician Assistant, Psychiatrist and other collaterals." -No counseling documentation provided for the months of December 2024 and January 2024. Only one counseling documented case note for the month of February 2025.</p> <p>Interview on 03/18/25 client #4 stated: -He had received services for 7 months. -He met with Counselor #1 once or twice a week.</p> <p>Interview on 03/19/25 Counselor #1 stated: -She was a Licensed Clinical Addiction Specialist (LCAS) - Associate. -She provided Counseling services at least 2 times a month. -The documentation of counseling notes may take time to get on the record.</p> <p>Interview on 03/19/25 Counselor #2 stated: -She was a LCAS-A. -She worked at the facility for approximately 2</p>	V 237		

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V 237	Continued From page 10 months. -Clients received counseling services 2 times a month. During interview on 03/19/25 the Program Director/Family Nurse Practitioner revealed: -The documentation from the counselors they were working on. -She knew counseling notes were going to be missing. -She had been talking with the counselors about the documentation and making sure the documentation was completed and placed in each client record in a timely manner.	V 237		
V 238	27G .3604 (E-K) Outpt. Opioid - Operations 10A NCAC 27G .3604 OUTPATIENT OPIOID TREATMENT - OPERATIONS. (e) The State Authority shall base program approval on the following criteria: (1) compliance with all state and federal law and regulations; (2) compliance with all applicable standards of practice; (3) program structure for successful service delivery; and (4) impact on the delivery of opioid treatment services in the applicable population. (f) Take-Home Eligibility. Any client in comprehensive maintenance treatment who requests unsupervised or take-home use of methadone or other medications approved for treatment of opioid addiction must meet the specified requirements for time in continuous treatment. The client must also meet all the requirements for continuous program compliance and must demonstrate such compliance during the specified time periods immediately preceding	V 238		

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V 238	Continued From page 11 any level increase. In addition, during the first year of continuous treatment a patient must attend a minimum of two counseling sessions per month. After the first year and in all subsequent years of continuous treatment a patient must attend a minimum of one counseling session per month. (1) Levels of Eligibility are subject to the following conditions: (A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at the clinic; (B) Level 2. After a minimum of 90 days of continuous program compliance, a client may be granted for a maximum of three take-home doses and shall ingest all other doses under supervision at the clinic each week; (C) Level 3. After 180 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 2, a client may be granted for a maximum of four take-home doses and shall ingest all other doses under supervision at the clinic each week; (D) Level 4. After 270 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 3, a client may be granted for a maximum of five take-home doses and shall ingest all other doses under supervision at the clinic each week; (E) Level 5. After 364 days of continuous treatment and a minimum of 180 days of continuous program compliance, a client may be granted for a maximum of six take-home doses and shall ingest at least one dose under supervision at the clinic each week; (F) Level 6. After two years of continuous treatment and a minimum of one year of	V 238		

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V 238	<p>Continued From page 12</p> <p>continuous program compliance at level 5, a client may be granted for a maximum of 13 take-home doses and shall ingest at least one dose under supervision at the clinic every 14 days; and</p> <p>(G) Level 7. After four years of continuous treatment and a minimum of three years of continuous program compliance, a client may be granted for a maximum of 30 take-home doses and shall ingest at least one dose under supervision at the clinic every month.</p> <p>(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:</p> <p>(A) A client's take-home eligibility is reduced or suspended for evidence of recent drug abuse. A client who tests positive on two drug screens within a 90-day period shall have an immediate reduction of eligibility by one level of eligibility;</p> <p>(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and</p> <p>(C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program.</p> <p>(3) Exceptions to Take-Home Eligibility:</p> <p>(A) A client in the first two years of continuous treatment who is unable to conform to the applicable mandatory schedule because of exceptional circumstances such as illness, personal or family crisis, travel or other hardship may be permitted a temporarily reduced schedule by the State authority, provided she or he is also found to be responsible in handling opioid drugs. Except in instances involving a client with a verifiable physical disability, there is a maximum of 13 take-home doses allowable in any two-week period during the first two years of continuous treatment.</p> <p>(B) A client who is unable to conform to the</p>	V 238		

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V 238	<p>Continued From page 13</p> <p>applicable mandatory schedule because of a verifiable physical disability may be permitted additional take-home eligibility by the State authority. Clients who are granted additional take-home eligibility due to a verifiable physical disability may be granted up to a maximum 30-day supply of take-home medication and shall make monthly clinic visits.</p> <p>(4) Take-Home Dosages For Holidays: Take-home dosages of methadone or other medications approved for the treatment of opioid addiction shall be authorized by the facility physician on an individual client basis according to the following:</p> <p>(A) An additional one-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed to each eligible client (regardless of time in treatment) for each state holiday.</p> <p>(B) No more than a three-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed to any eligible client because of holidays. This restriction shall not apply to clients who are receiving take-home medications at Level 4 or above.</p> <p>(g) Withdrawal From Medications For Use In Opioid Treatment. The risks and benefits of withdrawal from methadone or other medications approved for use in opioid treatment shall be discussed with each client at the initiation of treatment and annually thereafter.</p> <p>(h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each active opioid treatment client with a minimum of one random drug test each month of continuous treatment. Additionally, in two out of each three-month period of a client's continuous treatment episode, at least one random drug test</p>	V 238		

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V 238	<p>Continued From page 14</p> <p>will be observed by program staff. Drug testing is to include at least the following: opioids, methadone, cocaine, barbiturates, amphetamines, THC, benzodiazepines and alcohol. Alcohol testing results can be gathered by either urinalysis, breathalyzer or other alternate scientifically valid method.</p> <p>(i) Client Discharge Restrictions. No client shall be discharged from the facility while physically dependent upon methadone or other medications approved for use in opioid treatment unless the client is provided the opportunity to detoxify from the drug.</p> <p>(j) Dual Enrollment Prevention. All licensed outpatient opioid addiction treatment facilities which dispense Methadone, Levo-Alpha-Acetyl-Methadol (LAAM) or any other pharmacological agent approved by the Food and Drug Administration for the treatment of opioid addiction subsequent to November 1, 1998, are required to participate in a computerized Central Registry or ensure that clients are not dually enrolled by means of direct contact or a list exchange with all opioid treatment programs within at least a 75-mile radius of the admitting program. Programs are also required to participate in a computerized Capacity Management and Waiting List Management System as established by the North Carolina State Authority for Opioid Treatment.</p> <p>(k) Diversion Control Plan. Outpatient Addiction Opioid Treatment Programs in North Carolina are required to establish and maintain a diversion control plan as part of program operations and shall document the plan in their policies and procedures. A diversion control plan shall include the following elements:</p> <p>(1) dual enrollment prevention measures that consist of client consents, and either</p>	V 238		

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V 238	<p>Continued From page 15</p> <p>program contacts, participation in the central registry or list exchanges;</p> <p>(2) call-in's for bottle checks, bottle returns or solid dosage form call-in's;</p> <p>(3) call-in's for drug testing;</p> <p>(4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction;</p> <p>(5) client attendance minimums; and</p> <p>(6) procedures to ensure that clients properly ingest medication.</p> <p>This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to follow the take-home eligibility for 2 of 4 audited clients (#3 and #4). The findings are:</p> <p>Finding #1 Review on 03/18/25 and 03/19/25 of client #3's record revealed:</p> <ul style="list-style-type: none"> -Admission date of 11/18/24. -Diagnoses of Opioid Use Disorder. -Order dated 01/17/25, client #3's was currently taking methadone 110mg daily. -No positive Urine Drug Screens since the date of admission. <p>Interview on 03/18/25 client #3 stated:</p> <ul style="list-style-type: none"> -He received services for 5 months. -He transferred from another Methadone clinic. -He saw Counselor #1 at least 2 or 3 times a month. -He had completed drug screens. -He only had a take home dose on Sundays. -He would like to have additional take homes. 	V 238		

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V 238	<p>Continued From page 16</p> <p>Finding #2 Review on 03/18/25 and 03/19/25 of client #4's record revealed:</p> <ul style="list-style-type: none"> -Admission date of 08/14/24. -Diagnoses of Opioid Use Disorder, Depression, Hypertension and Tobacco Use. -Order dated 08/14/24, client #4 was currently taking methadone 180mg daily. -No positive Urine Drug Screen since 09/27/24. <p>Interview on 03/18/25 client #4 stated:</p> <ul style="list-style-type: none"> -He had received services for 7 months. -He met with Counselor #1 once or twice a week. -He only had a Sunday take home. <p>Interview on 03/19/25 Counselor #1 stated:</p> <ul style="list-style-type: none"> -Some clients want take homes. -She met with the clients at least 2 times a month. -She wanted clients to have take homes. <p>Interview on 03/18/25 and 03/19/25 the Program Director revealed:</p> <ul style="list-style-type: none"> -She was told they were not allowed to do take-home medication from State Opioid Treatment Authority (SOTA). -A new waiver was in effect for take-home medication and she had sent all the information for approval and she had not received any information. -The agency did have clients that met the requirements for the take-home medication and would love the opportunity to have the take-home eligibility. <p>Interview on 03/19/25 the Chief Operating Officer stated:</p> <ul style="list-style-type: none"> -We were told from SOTA that we were not allowed to offer any take-home medications to any of the clients. 	V 238		

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V 238	Continued From page 17 -A select few of the clients do qualify and have met the criteria for take-home medications and would love to have the opportunity for take-home medications. -They will follow the guidelines of the rules for the take-home qualifications and begin the process for the take-home medications for the clients that are eligible.	V 238			