Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL070-063	A. BUILDING: _____ B. WING _____	10/16/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
JK2C, LLC DBA BHG ELIZABETH CITY TREAT	105 MEDICAL DRIVE ELIZABETH CITY, NC 27909

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V 000	INITIAL COMMENTS An annual and complaint survey was completed on 10/16/24. The complaint was unsubstantiated (Intake #NC00221610). Deficiencies were cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. This facility has a current census of 249. The survey sample consisted of audits of 12 current clients.	V 000		
V 234	27G .3602 Outpt. Opiod Tx. - Definitions 10A NCAC 27G .3602 DEFINITIONS In addition to terms defined in G.S. 122C-3 and Rule .0103 of this Subchapter, the following definitions shall also apply: (1) "Capacity management system" is a computerized database, maintained at the Office of the North Carolina State Authority for governing treatment of opioid addiction with an opioid drug, which ensures timely notification of the State whenever a program reaches 90 percent of its capacity to treat intravenous drug users, and to make any excess treatment capacity available. The requirement to have a capacity management system in 45 C.F.R. Part 96.126(a), the Substance Abuse Prevention and Treatment Block Grant, is incorporated by reference and includes all subsequent amendments and editions and may be obtained from the Substance Abuse Services Section of DMH/DD/SAS. The computerized system shall ensure that a continuous updated record of all such reports is maintained and that excess capacity information shall be available to all other programs. (2) "Central registry" is a computerized	V 234	RECEIVED NOV 6 2024 DHSR-MH Licensure Sect	

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Ellaff TITLE Program Director (X6) DATE 10.30.24

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V 234	Continued From page 1 patient database, maintained at the Office of the North Carolina State Authority for governing treatment of opioid addiction with an opioid drug. The purpose of the database is to prevent multiple methadone treatment program enrollments; thereby lessening the possibility of methadone diversion for illicit use. (3) "Waiting list management system" is a component of the capacity management system whereby systematic reporting of treatment demand is maintained. The data required for the waiting list management component of the capacity shall include a unique patient identifier for each intravenous drug user seeking treatment, the date initial treatment was requested, and the date the drug user was removed from the waiting list. The waiting list management system requirement in 45 CFR 96.126(c) is incorporated by reference and includes subsequent amendments and editions of the referenced material. It may be obtained from the Substance Abuse Services Section of DMH/DD/SAS. (4) "Methadone hydrochloride" (hereafter referred to as methadone) is a synthetic narcotic analgesic with multiple actions quantitatively similar to those of morphine, most prominent of which involves the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value or analgesia and sedation are detoxification or temporary maintenance in narcotic addiction. The methadone abstinence syndrome, although quantitatively similar to that of morphine differs in that the onset is slower, the course more prolonged, and the symptoms are less severe. (5) "Other medications approved for use in opioid treatment" are those medications approved by the Food and Drug Administration for use in	V 234		

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V 234	Continued From page 2 opioid treatment and also approved for accepted medical uses under the North Carolina Controlled Substances Act. (6) "Program compliance for purposes of take-home eligibility" is determined by: (a) absence of recent drug abuse; (b) clinic attendance; (c) absence of behavioral problems at the clinic; (d) stability of the patient ' s home environment and social relationships; (e) length of time in comprehensive maintenance treatment; (f) assurance that take-home medication can be safely stored within the patient's home; and (g) evidence the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion. (7) "Recent drug abuse for purposes of determining program compliance" is established by evidence of the misuse of either opioids, methadone, cocaine, barbiturates, amphetamines, delta-9-tetrahydrocannabinol (hereafter referred to as THC), benzodiazepines or alcohol documented in the results of two random drug tests conducted within the same 90-day period of continuous treatment. (8) "Counseling session in Outpatient Opioid Treatment" is a face-to-face or group discussion of issues related to and of progress toward a client ' s treatment goals that is conducted by a person as specified in Rule .3603, Paragraph (a) of this Section.	V 234		

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V 234	Continued From page 3 This Rule is not met as evidenced by: Based on record review and interview, the facility failed to ensure 3 of 12 audited clients (#1206, #1132 & #1773) had counseling sessions to discuss positive drug screenings. The findings are: Review on 10/15/24 of client #1206's record revealed: - admitted 10/8/24 - Diagnosis: Opioid Disorder - Counselor: Program Director/Clinical Director - Drug screenings with the following results: - 10/8/24: Positive for fentanyl, marijuana (THC) and opiates - 9/23/24: Positive for THC and opiates - 9/10/24: positive for THC and opiates - last documented counseling session was 8/29/24 Review on 10/15/24 of client #1132's record revealed: - admitted 10/4/22 - Diagnosis: Opioid Disorder - Counselor: Program Director/Clinical Director - Drug screenings with the following results: - 9/11/24, 9/18/24, 9/30/24 & 10/7/24 positive for THC - last documented counseling session was 8/30/24 Review on 10/15/24 of client #1773's record revealed: - Admitted 1/10/23 - Diagnosis of Opioid Dependence Uncomplicated - Drug screenings with the following results: - 8/22/24: Positive for fentanyl - 8/28/24: Positive for cocaine & fentanyl	V 234		

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V 234	Continued From page 4 - 9/5/24: Positive for fentanyl - 9/10/24: Positive for fentanyl - 9/17/24: Positive for fentanyl & opiates - 9/23/24: Positive for fentanyl - 10/3/24: Positive for fentanyl, opiates & cocaine - 10/8/24: Positive for fentanyl & opiates - No documentation of counseling sessions for the listed positive drug screenings Interview on 10/15/24 client #1773 reported: - Had received treatment at the facility for two years - Her counselor was the Program Director/Clinical Director - Had weekly drug screenings - Had a drug screening that was positive for heroine last week - Hadn't meet with her counselor about the positive drug screening Interview on 10/15/24 the Program Director/Clinical Director reported: - Just returned from a two week vacation - Filled in as a counselor and saw clients when needed - Currently had 32 clients on her caseload - Have a new counselor onboarding and she will take a full caseload - Client #1773 former counselor resigned and she was switched to her caseload prior to her vacation - Was unaware client #1773 didn't have counseling sessions discussing her positive drug screenings	V 234	On October 15, 2024, the Program Director revised and implemented a plan to ensure all deficiencies are addressed and that corrective actions are sustained. This includes hiring a new counselor to assist with the Program Director's caseload and implementing a "counselor overflow" monitor to address immediate patient needs. The Program Director will work closely with Human Resources and Recruitment, conducting bi-weekly follow-ups to expedite the hiring process. To maintain patient care in the interim, clinical team members are focusing on effective scheduling and time management until staffing reaches full capacity. Additionally, the Lead Counselor and Clinical Supervisor will conduct weekly audits to monitor missed appointments and identify and address any further needs. The Program Director will communicate the results of all audits while updating the Regional Director at least every two weeks. In addition, the Program Director will report audit results and hiring progress to the Regulatory Team at least monthly for the next six months for internal monitoring.	Plan in place October 15th. Hiring process ongoing.
V 235	27G .3603 (A-C) Outpt. Opiod Tx. - Staff 10A NCAC 27G .3603 STAFF	V 235		

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V 235	Continued From page 5 (a) A minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients and increment thereof shall be on the staff of the facility. If the facility falls below this prescribed ratio, and is unable to employ an individual who is certified because of the unavailability of certified persons in the facility's hiring area, then it may employ an uncertified person, provided that this employee meets the certification requirements within a maximum of 26 months from the date of employment. (b) Each facility shall have at least one staff member on duty trained in the following areas: (1) drug abuse withdrawal symptoms; and (2) symptoms of secondary complications to drug addiction. (c) Each direct care staff member shall receive continuing education to include understanding of the following: (1) nature of addiction; (2) the withdrawal syndrome; (3) group and family therapy; and (4) infectious diseases including HIV, sexually transmitted diseases and TB. This Rule is not met as evidenced by: Based on interviews, the facility failed to ensure a minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients. The findings are Interview on 10/15/24 the Program Director/Clinical Director stated:	V 235	On October 15, 2024, Program Director implemented a plan to address staffing and patient care needs. This plan includes ongoing advertising for CADC and CADC-I positions to attract qualified candidates. Currently, two counseling positions are open to maintain a caseload ratio of 50 patients per counselor, with one new hire scheduled to begin on November 4, 2024, after completing onboarding. Patient care and Urine Drug Screen (UDS) monitoring will be closely overseen, with nurses supporting the clinical department as additional counselors are brought on board. The Program Director will review clinical needs weekly with the Regional Director and conduct weekly audits of caseloads. In addition, the Program Director will report audit results and hiring progress to the Regulatory Team at least monthly for the next six months for internal monitoring. This plan ensures continuous quality care and is under active management to address evolving clinical requirements.	Plan in place October 15th. Hiring process ongoing.

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V 235	Continued From page 6 -Not currently fully staffed. -Had a counselor to recently leave and currently onboarding a new counselor. -Had to carry a caseload and currently had 32 on her load. -Staff #1 had 70, Staff #2 had 73 and Staff #3 had 64. -They had these high caseloads for the last month. -Very difficult to get counselors hired with the new requirements from the MCO. -Counselors are now required to pass the NC state board exam prior to delivery of services. -In the past, the counselors had two years to complete the required board exam. Interview on 10/15/24 staff #1 stated: -Currently had a case load of 70 clients. -A new counselor is onboarding and did not have a caseload. -Had good time management, so the case load is not too much to handle.	V 235		
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	V 238		

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V 238	Continued From page 7 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 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;	V 238		

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V 238	Continued From page 8 (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 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 (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. (2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility: (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; (B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and (C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program. (3) Exceptions to Take-Home Eligibility: (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	V 238		

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V 238	Continued From page 9	V 238		

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.

(B) A client who is unable to conform to the 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.

(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:

(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.

(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.

(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

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V 238	Continued From page 10 treatment and annually thereafter. (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 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. (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. (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. (k) Diversion Control Plan. Outpatient Addiction	V 238		

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V 238	Continued From page 11 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: (1) dual enrollment prevention measures that consist of client consents, and either program contacts, participation in the central registry or list exchanges; (2) call-in's for bottle checks, bottle returns or solid dosage form call-in's; (3) call-in's for drug testing; (4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction; (5) client attendance minimums; and (6) procedures to ensure that clients properly ingest medication. This Rule is not met as evidenced by: Based on observation, record review and interview the facility failed to ensure clients properly ingested medications to prevent diversion for 3 of 12 clients (#2087, #1206 & #1821) A. Observation on 10/15/24 at 6:55am revealed client #2087 at the dosing window: - the nurse crushed the Buprenorphine (Bup) - client #2087 left the window without the Bup fully dissolved B. Review on 10/15/24 of client #1206's record revealed: - admitted 10/8/24 - Diagnosis: Opioid Disorder	V 238	On October 15, 2024, nursing staff received re-education on the administration of Buprenorphine and Methadone, with a focus on policies related to diversion, including the required observation of patient ingestion of Buprenorphine doses. This re-training was conducted by the Nurse Practitioner (NP) and Program Director (PD). The PD is responsible for ongoing monitoring to ensure adherence to these policies. The Program Director will perform routine, random audits to ensure process is being followed. Results of these audits will be shared with the Regional Director at least monthly. In addition, the Program Director will report audit results to the Regulatory Team at least monthly for the next six months for internal monitoring.	October 15,2024

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V 238	Continued From page 12 During interview on 10/15/24 client #1206 reported: - was currently on 12mg (milligrams) of Bup - apologized for the Bup in his mouth while he was being interviewed - the nurse crushes it a the window, so it does not take long to dissolve C. Review on 10/15/24 of client #1821's record revealed: - admitted 6/14/23 - diagnosis: Opioid Disorder During interview on 10/15/24 client #1821 reported: - was currently on 12mg of Bup - "they (nurses) crush it for me, put it under my tongue and then walk out" - "I've had it under my tongue the whole time I've been talking to you" During interview on 10/15/24 the Registered Nurse reported: - for the first 30 days, would observe clients until the Bup was fully dissolved in their mouth - after 30 days, clients no longer had to wait at the nurse's station until the Bup dissolved During interview on 10/15/24 the Program Director/Clinical Director reported: - clients were supposed to wait at the nurse's station until the Bup fully dissolved - "that's always been our policy and I'm a little shocked that its not happening" During interview on 10/15/24 the Nurse Practitioner reported: - "Bup supposed to be dissolved in the dosing room prior to them (clients) leaving"	V 238		

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	MHL070-063	A. BUILDING: _____ B. WING _____	10/16/2024

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V 238	Continued From page 13 - a risk could be an increased dose from clients that "spit it into each others mouths"	V 238		
V 536	27E .0107 Client Rights - Training on Alt to Rest. Int. 10A NCAC 27E .0107 TRAINING ON ALTERNATIVES TO RESTRICTIVE INTERVENTIONS (a) Facilities shall implement policies and practices that emphasize the use of alternatives to restrictive interventions. (b) Prior to providing services to people with disabilities, staff including service providers, employees, students or volunteers, shall demonstrate competence by successfully completing training in communication skills and other strategies for creating an environment in which the likelihood of imminent danger of abuse or injury to a person with disabilities or others or property damage is prevented. (c) Provider agencies shall establish training based on state competencies, monitor for internal compliance and demonstrate they acted on data gathered. (d) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course. (e) Formal refresher training must be completed by each service provider periodically (minimum annually). (f) Content of the training that the service provider wishes to employ must be approved by the Division of MH/DD/SAS pursuant to Paragraph (g) of this Rule. (g) Staff shall demonstrate competence in the	V 536		

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V 536	Continued From page 14 following core areas: (1) knowledge and understanding of the people being served; (2) recognizing and interpreting human behavior; (3) recognizing the effect of internal and external stressors that may affect people with disabilities; (4) strategies for building positive relationships with persons with disabilities; (5) recognizing cultural, environmental and organizational factors that may affect people with disabilities; (6) recognizing the importance of and assisting in the person's involvement in making decisions about their life; (7) skills in assessing individual risk for escalating behavior; (8) communication strategies for defusing and de-escalating potentially dangerous behavior; and (9) positive behavioral supports (providing means for people with disabilities to choose activities which directly oppose or replace behaviors which are unsafe). (h) Service providers shall maintain documentation of initial and refresher training for at least three years. (1) Documentation shall include: (A) who participated in the training and the outcomes (pass/fail); (B) when and where they attended; and (C) instructor's name; (2) The Division of MH/DD/SAS may review/request this documentation at any time. (i) Instructor Qualifications and Training Requirements: (1) Trainers shall demonstrate competence by scoring 100% on testing in a training program	V 536		

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V 536	Continued From page 15 aimed at preventing, reducing and eliminating the need for restrictive interventions. (2) Trainers shall demonstrate competence by scoring a passing grade on testing in an instructor training program. (3) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course. (4) The content of the instructor training the service provider plans to employ shall be approved by the Division of MH/DD/SAS pursuant to Subparagraph (i)(5) of this Rule. (5) Acceptable instructor training programs shall include but are not limited to presentation of: (A) understanding the adult learner; (B) methods for teaching content of the course; (C) methods for evaluating trainee performance; and (D) documentation procedures. (6) Trainers shall have coached experience teaching a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least one time, with positive review by the coach. (7) Trainers shall teach a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least once annually. (8) Trainers shall complete a refresher instructor training at least every two years. (j) Service providers shall maintain documentation of initial and refresher instructor training for at least three years. (1) Documentation shall include: (A) who participated in the training and the	V 536		

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V 536	Continued From page 16 outcomes (pass/fail); (B) when and where attended; and (C) instructor's name. (2) The Division of MH/DD/SAS may request and review this documentation any time. (k) Qualifications of Coaches: (1) Coaches shall meet all preparation requirements as a trainer. (2) Coaches shall teach at least three times the course which is being coached. (3) Coaches shall demonstrate competence by completion of coaching or train-the-trainer instruction. (l) Documentation shall be the same preparation as for trainers. This Rule is not met as evidenced by: Based on record review and interview the facility failed to ensure one of four audited staff (the Program Director/Clinical Director , Staff #1, Licensed Practical Nurse-LPN and Registered Nurse-RN) training in Alternative to Restrictive Interventions were current. The findings are: Review on 10/15/24 of the Program Director/Clinical Director's record revealed: -Hire date of 10/22/21 -No current Alternative to Restrictive Intervention present. Review on 10/15/24 of Staff #1's record revealed: -Hire date of 5/26/24	V 536	All employees are scheduled to complete their annual Nonviolent Crisis Intervention (NCI) training on November 21, 2024. This in-hous[redacted]be led by certified trainer [redacted] ensuring active engag staff, all employees will sign off on the training roster, showing attendance of the training. Roster will be made available to view by regulators. The Program Director (PD) will monitor the training schedule and oversee ongoing NCI training for newly onboarded employees. A quarterly education audit will be completed by the Program Director and shared with the Regional Director. Quarterly audit will also be reported to the Regulatory Team for minimum of two quarters for internal monitoring.	November 21, 2024

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V 536	Continued From page 17 -No current Alternative to Restrictive Intervention present Review on 10/15/24 of the LPN's record revealed: -Hire date of 3/25/23 -No current Alternative to Restrictive Intervention present Review on 10/15/24 on of the RN's record revealed: -Hire date of 10/22/21 -No current Alternative to Restrictive Intervention present Interview on 10/15/24 the Program Director/Clinical Director stated: -Staff #1 was hired a few months ago, but did not have Alternative to Restrictive Interventions as of now. -She was scheduled for the next training. -Was not aware she needed the training prior to delivery of service. -They have a new system where the personnel trainings are stored and had not used it yet. -Will have to contact Human Resources to have them to find the staff trainings. -Will email the trainings once she received them. As of close of business on 10/16/24, the training certificates for Alternative to Restrictive Interventions were not received.	V 536		