STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 000	INITIAL COMMENTS A complaint survey was completed on 2/2/21. The complaints were substantiated. (# NC171796, NC172651). Deficiencies were cited. The current census was 93. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment.	V 000		
V 118	27G .0209 (C) Medication Requirements 10A NCAC 27G .0209 MEDICATION REQUIREMENTS (c) Medication administration: (1) Prescription or non-prescription drugs shall only be administered to a client on the written order of a person authorized by law to prescribe drugs. (2) Medications shall be self-administered by clients only when authorized in writing by the client's physician. (3) Medications, including injections, shall be administered only by licensed persons, or by unlicensed persons trained by a registered nurse, pharmacist or other legally qualified person and privileged to prepare and administer medications. (4) A Medication Administration Record (MAR) of all drugs administered to each client must be kept current. Medications administered shall be recorded immediately after administration. The MAR is to include the following: (A) client's name; (B) name, strength, and quantity of the drug; (C) instructions for administering the drug; (D) date and time the drug is administered; and (E) name or initials of person administering the drug. (5) Client requests for medication changes or checks shall be recorded and kept with the MAR	V 118		

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V 118	Continued From page 1 file followed up by appointment or consultation with a physician. This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to assure medication was administered by trained staff for 1 of 1 audited former client (FC #6), failed to administer medications on the written order of authorized person affecting 2 of 5 audited clients (Client #3 and Client #4) and 1 of 1 former client (FC #6) and the Licensee (Program Sponsor/Registered Nurse) failed to demonstrate competency for medication administration for 1 of 1 former client (FC #6). The findings are: Review on 1/28/21 of Facility's Exception Requests submitted to SOTA (State Opioid Treatment Authority) revealed: -Facility submitted requests on a monthly basis beginning 3/18/20 through January 2021 to be included in the NC (North Carolina) blanket exceptions that would "allow blanket exceptions for all stable patients in an OTP [outpatient treatment program] to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder. The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication ...Per our internal protocol, each client approved under this exception will be staffed and screened by our medical director along with counseling and	V 118		

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V 118	Continued From page 2 nursing staff to ensure that they are appropriate for this privilege." Record review on 1/7/21 for Client #3 revealed: -Date of admission was 5/4/20 and readmitted 9/29/20 with diagnoses of opioid use disorder, enlarged prostate, arthritis, Afib (Atrial Fibrillation), history of alcohol dependence. -History and physical signed by the medical director on 9/29/20 revealed prescriptions for Flomax, carvedilol, Eliquis, furosemide, tamsulosin, B6 and diazepam. -doctor's order dated 5/5/20-expired on 8/31/20-"Per state of emergency due to COVID 19 outbreak statewide exception patient may receive up to 28 takeouts. Patient's record has been reviewed and patient has been assessed as stable enough to receive additional takeouts." - all orders indicate Phase Level 1. -review of MAR revealed: -10/2/20 - 2 TO (take outs) -10-9/20 - 2 TO -10/16/20 - 2 TO -10/23/20- 2 TO -10/30/20- 4 TO -11/4/20 - 6 TO -11/11/20 - 6 TO -11/18/20 - 6 TO -11/25/20 - 1 TO -11/27/20 - 4 TO -12/2/20-1/6/21 received 6 TOs each week. -No documentation was provided of a screening or assessment by medical director, counseling or nursing staff to determine appropriateness for take-homes. -No tracking of individuals with exceptions was provided. Interview on 1/6/21 with Client #3 revealed: -had been at clinic 5 months- he did not transfer.	V 118		

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V 118	Continued From page 3 -currently at 60mg (milligrams) and had 6 take homes. Record review on 1/8/21 for Client #4 revealed: -Date of admission 4/7/20 with diagnoses of severe opioid use disorder, Post Traumatic Stress Disorder, Anxiety and Depression. -doctor's order dated 4/8/20 and expired on 8/31/20 allowed for COVID exceptions-"Per state of emergency due to COVID 19 outbreak statewide exception pt (patient) may receive up to 28 takeouts. Patient's record has been reviewed and pt has been assessed as stable enough to receive additional takeouts." -doctor's orders dated 5/22/20 revealed increase - "140mg to 10mg." No correction order was available. -Review of MAR revealed: -4/10/20-5/15/20 received 2 TOs. -5/22/20- 3 TOs -5/29/20 - 2 TOs -6/5/20- 2 TOs -6/12/20- 2 TOs -6/24/20 -6 TOs -7/1/20- 6 TOs -7/8/20 - 6 TOs -7/15/20- 6 TOs -7/22/20 - 11 TOs -8/3/20 - 1 TO -8/5/20- 1 TO -8/7/20 - 2 TOs -8/10/20- 1 TO -8/12/20- 6 TOs -8/19/20 -6 TOs -8/27/20- 6 TOs -9/4/20- 5 TOs -9/12/20- 1 TO -9/19/20 -1 TO -9/25/20 - 2 TOs -10/3/20-12/10/20 received 1 TO each week	V 118		

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V 118	Continued From page 4 -12/11/20 -2 TOs -12/14/20-1/12/21 received 1 TO each week -All orders indicated Phase 1. -No documentation was provided of a screening or assessment by medical director, counseling or nursing staff to determine appropriateness for take-homes. -No tracking of individuals with exceptions was provided. Interview on 1/6/21 with Client #4 revealed: -began several months ago -current dose 160mg - no take homes -never had Program Director (PD) dose-never seen PD dose anyone- Have had Program Sponsor/Registered Nurse (PS/RN) dose -dosed in parking lot due to COVID screening- no difference in dosing Record review on 1/8/21 for Former Client (FC) #6 revealed: Date of admission 3/16/20 with diagnosis of opioid use disorder Date of discharge 8/3/20. Review of doctor's order revealed: -signed on 3/16/20 -"transfer from [local facility] on level 3 on methadone 200mg po [by mouth] q [once] daily" -signed on 3/19/20- "expires on 1/1/0001- Per state of emergency due to outbreak of COVID 19 per statewide exception patient may receive up to 28 takeouts, record has been reviewed and patient has been assessed as stable enough to receive additional doses." -signed on 4/10/20- "expires on 1/1/0001- patient is missing take out medication- dose methadone 120mg 4/10/20, dose methadone 120mg at 4/11/20, dose methadone 120mg on 4/13/20" -signed on 4/13/20- "expires on 1/1/0001- dose methadone 160mg on 4/14/20 and 4/15/20- dose	V 118		

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methadone 200mg on 4/16/20- continue methadone 200mg q daily thereafter- phase down to level 1 for a minimum of 30 days"
Review of MAR revealed:
-4/10/20- 120mg dose marked as TO
-4/11/20- 120mg dose marked as TO
-4/12/20- patient absent
-4/17/20 - 2 TOs
-4/20/20 - 2 TOs
-4/23/20 - 3 TOs
-4/27/20 - 2 TOs
-4/30/20 - 3 TOs
-5/4/20 - 2 TOs
-5/7/20 - 3 TOs
-no documentation to explain why no order was written to continue dosing on 4/12/20.
-No documentation was provided of a screening or assessment by medical director, counseling or nursing staff to determine appropriateness for take-homes.
-No tracking of individuals with exceptions was provided.

Review on 1/25/21 of hospital records for FC #6 revealed:
-4/10/20-FC #6 was seen at Emergency Department via Emergency Medical Services for chest pain, shortness of breath-completed chest xray, EKG, flu test
-admit 3:42pm- discharge 7:25pm - likely upper respiratory infection

Multiple attempts on 1/22/21 to reach FC #6 revealed no answer and no ability to leave voice mail.

Review on 1/4/21 of investigative report by SOTA (State Opioid Treatment Authority) revealed:
-"On 12/8/20 SOTA Administrator and SOTA Coordinator performed an unannounced site visit

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to Pisgah Recovery Services to investigate this complaint. We requested dosing records for all patients during the month of April and were provided access to Methasoft from the [Program Sponsor/Registered Nurse (PS/RN)].
-Audit report for 4/11/2020, shows that one patient was dosed that day at 10:03am during a time that the clinic was closed to all other staff and patients. (Audit Report in Methasoft will show the credentials of the person and the IP address from which they logged in.) Further review of this patient's medical record indicated the following:
-On 4/10/20 there was a note from the dosing nurse filling in due to [PS/RN]'s trip to [another North Carolina city], that this patient [FC #6] returned early stating that his COVID-19 take homes [TH] had spilled and that he needed replacement doses. This patient had 6 THs of 200mg [milligrams] MTD [methadone]. The nurse contacted the [Medical Director (MD)] to report the information and the decision was made to reduce [FC #6]'s dose to 120mg and for him to dose in the clinic on 4/10/20, 4/11/20 and 4/13/20. The clinic is closed on Sunday and no preparation was made for this patient to dose on 4/12/20.
-The fill in nurse dosed [FC #6] around 8:00am on 4/10/20 and documented the reported spill as the reason for the re-dose that was already accounted for due to COVID-19 take homes.
-All other patients had take homes for Saturday 4/11/20 and no staff were scheduled to work that day. [PS/RN] remained out of town.
-On 4/11/20, [FC #6] made contact with the clinic staff to determine how he would receive his dose for that day because when he came to the clinic during dosing hours, it was closed.
-Log in records show that user ID [PS/RN] signed into computer [LOGIN #1] at 9:17. This was presumably done on his laptop out of town.
-Log in records show that user ID [Program

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V 118	Continued From page 7 Director (PD)] signed into computer [LOGIN #2] at 9:43am. This was presumably done on the computer in [PD]'s office at the clinic. -Log in records show that user ID [PS/RN] signed into computer [LOGIN #3] at 9:45am. This computer is different from the computer [PS/RN] used at other times throughout that day and was around the time of this patient's dose at the clinic. This indicates that this machine is located at the clinic and that the person signing in was not [PS/RN]. This was presumably [PD] logging in as [PS/RN] at the nurse's station in order to pump the dose for [FC #6]. - [FC #6] was dosed around 10am in the parking lot of the clinic. -At 10:11am there is a nurse note entered from the log in on the machine [LOGIN #3] that states "patient dosed in car per COVID-19 precautions, telenursing direct observation and supervision of all elements of medication administration." This note was presumably entered by [PD] who was logged in as [PS/RN] at the time of dosing. -This note was later amended at 9:37pm on computer [LOGIN #1] to read "Patient dosed methadone 120mg in parking lot due to risk of exposure to COVID-19. Instructed to bring hospital paperwork on his return to the clinic on 4/13/20." The mention of telenursing was removed from this documentation and the appearance is that [FC #6] was dosed by [PS/RN] on site. -This note is also the first and only mention of any hospitalization justifying re-dosing, the car dosing or the change in protocol for this patient to be dosed when the clinic was otherwise closed. There was no documentation later uploaded in the medical record to support that this patient was hospitalized at any point. -[FC #6] was not dosed on Sunday 4/12/20 and there is no indication in the medical record that	V 118		

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any attempt was made to set up guest dosing or provide a take home for [FC #6].

-[FC #6] returned on Monday 4/13/20 to dose at 120mg.

-Order was placed for [FC #6] to dose at 160mg on 4/14/20 and 4/15/20 then increase back to his stable dose of 200mg on 4/16/20.

-Interview with [PD] about substantiated complaint and findings:

-[PD] denied that he has ever dosed a patient until he was presented with the evidence of his log in from his computer at the clinic less than 2 minutes before user [PS/RN] logged in at the nurse station. At that point, he stated that he did remember that particular situation and reported that [PS/RN] remotely logged in to dose [FC #6] through his laptop. This is not supported by the evidence of the timestamped log in from the computer at the dosing area. The only way for the medication to be pumped would be for the person physically at the clinic, [PD], to obtain the methadone out of the safe, log into the computer present at the clinic, hook up the bottle to the computer and pump the dose.

-[PD] reported that he was on a video call with [PS/RN] at the time and that [PS/RN] walked him through how to dose [FC #6]. He also indicated that [PS/RN] was able to see and assess [FC #6] in real time via the video/audio connection.

-Interview with [PS/RN] about substantiated complaint and findings:

-[PS/RN] adamantly denied that he would have ever directed [PD] to dose a patient in his absence or that [PD] would do that himself. When presented with the fact that [PD] had confessed to what happened, [PS/RN] reported that he did remember that particular situation. He stated that he believed it would be okay under the Emergency Nursing Act to direct a non-nurse to dose this patient. He stated that he did observe

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V 118	Continued From page 9 [FC #6] via telenursing to assess [FC #6] before and after [PD] administered the dose to him. -Interview with [MD] about substantiated complaint and findings: -[MD] reported that he was told this patient had been hospitalized and his take homes did not return home with [FC #6]. He stated that he reduced the dose to 120mg because they could not verify that [FC #6] no longer had his take homes. He communicated a verbal order on 4/10/20 to the fill in nurse that this patient is to dose in the clinic at 120mg on 4/10/20, 4/11/20 and 4/13/20. There was no order written for dosing on Sunday 4/12/20 and [FC #6] subsequently missed his dose this day. -Interview with [personnel] of the NC Board of Nursing: -The Emergency Nursing Act does not allow for the nurse to direct a non-nurse to do a nursing function that would otherwise not be supported by the policies of the agency or state and federal guidance. -Furthermore, the idea that this was an "emergency situation" is false. The program knew [FC #6] had "spilled" his take home doses early in the morning on Friday 4/10/20 with over 24 hours to determine a course of action for this client that could include: -A nurse to meet the client at the clinic to dose on Saturday 4/11/20 -A replacement take home for Saturday 4/11/20 and Sunday 4/12/20 -Guest dosing orders to dose at another program on Saturday 4/11/20 and Sunday 4/12/20 -Referral to the local emergency department for dosing -The fact that plans were not made to dose this patient on Sunday 4/12/20 also indicates that missing a dose is not considered to be an	V 118		

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emergency to this program.
-SOTA findings and interviews substantiate the complaint made on 11/17/20 by the anonymous complainant. From the records, it is clear that [PD] who is not qualified nor authorized to administer schedule II narcotics, dosed this patient under the username of [PS/RN] in the Methasoft System. The note at the time indicated the telenursing encounter with [PS/RN] over the phone with [FC #6] in the parking lot as [PD] administered the medication. However this note was later amended to remove the telenursing statement and to instead suggest that this patient was dosed by [PS/RN] on site during a time that the clinic was otherwise closed due to [FC #6]'s hospitalization. Those hospitalization records were subsequently never included in the medical record. Furthermore, efforts were made to cover up this event, [PS/RN] and [PD] attempted to state that this adjustment to the protocol was due to an emergency situation. However, the fact that no plans were made to attempt to dose this patient on Sunday 4/12/20 indicate that a missed day of dosing is not considered to be an emergency by this program's standards." Signed by SOTA coordinator on 12/16/20.

Interview on 1/6/21 with Nurse #1 revealed:
-was a LPN (Licensed Practical Nurse) and was hired in May- worked 6 days a week from 5:30-11:30am and Saturday 7-9am.
-she had not missed a day since she had been hired.
-a new RN(Registered Nurse) had recently been hired and was training at sister clinic.
-would conduct COWS (clinical opiate withdrawal scale) from dosing window. If she suspected a patient impairment, she would call PS/RN or Nurse at sister clinic but she had not seen anyone impaired.

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-if patient requested an increase or decrease she would submit internally in EMR (Electronic Medical Record) with COWS. It would be processed the next day or whenever the Medical Director (MD) signs the order. The MD usually reviewed over night and signed.
-The PD had not dosed anyone since she had been here.

Interview on 1/25/21 with the PD revealed:
-Facility began seeing clients 3/2/20
-he was the only one who worked that Saturday 4/11/20- had given everyone Take homes for Saturday and Sunday
-had a PRN (as needed) nurse who filled in sometimes, not often in March/April-not working now
-she worked on 4/10/20 but not 4/11/20.
-no clients were scheduled to come in on Saturday 4/11/20 but "we still had to open".
-FC #6 called the clinic- the PD called the PS/RN and the PS/RN called the MD. He didn't remember the specifics about the situation because it was so long ago.
"I dosed [FC #6] in the parking lot on 4/11/20"- he did not receive any TOs (takeouts).
"4/10 and 4/11/20 were not TOs as indicated on the MAR- marked incorrectly.
"As I recall he was given an option to go to the [sister Clinic] on Sunday but he declined."
"If [FC #6] had wanted to go to [sister clinic], I would have had [the MD] sign a guest dosing order."
"[The PS/RN] talked to [the MD], not sure exactly what was arranged- I wasn't involved in it."
-"Medical director determines on case by case basis for how many take outs are given-he would evaluate any supporting evidence a patient provides."
-COVID exceptions-standard- stable on dose -get

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up to 6 take outs regardless of UDS
-"no one would get take out until they were stable on their dose-2-4 weeks-during induction phase as they may need increase."
-if stable and clean screens could get up to 13 TOs.
-up to 27 TOs for stability and time in treatment (2 years).
-"We've been putting flags in the system such as 'can get up to _# of TOs'."
- the PS/RN entered dosing comments "COVID 19 blanket exception eligible for additional takeouts".
- "The blanket exceptions by definition cover all patients during the time period indicated, including new patients that are admitted during that timeframe. Neither CSAT (Center for Substance Abuse Treatment) or the SOTA have indicated that exceptions need to be tracked on an individual level other than what is recorded in the individual MAR."

Interview on 1/28/21 and 1/29/21 with PS/RN revealed:
-"I was not just on the phone with [PD] but real time video-observing every single step."
-"Still feel it was the best thing we could do in the circumstance."
"-NC Nursing Board says as long as I'm within my scope of practice I can do the same via telemedicine."
-"[the PD] was acting as my hands-he didn't really do anything-called 'unlicensed assisted personnel'."
-"[the PD] didn't dose anyone I did."
-"I dictated the note to him. I documented because I did it."
-"used video cameras from internal secure system-can't store recordings past 21 days. I saw him remove the bottle from the vault, measure,

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pump twice and show me the dose".
-"don't remember how we learned of lost takeouts-long time ago"
-he called [the MD] who decided to reduce the dose.
-he was under the impression Former Nurse #2 was supposed to come in that Saturday.
-"we were short staffed but opened on Saturday because we had to be open."
-"[FC #6] had been a level 6 previously."
-"I thought about every piece of this to make sure this patient got what he needed."
-"we were 1 off, 1 time."
- the number of takeouts was determined by "looking at UDS-if positive for narcotics-more liberal up front of this blanket exception but have gotten better at managing this. We look at stability, participation in treatment, longevity. It's a case by case basis-don't know what we're doing but weigh out COVID exposure. We know our patients. We've had very little issue."
-"usually only gave our new patients no more than 1 weeks' worth [of takeouts]. Some old patients that have been here awhile may get up to 2 weeks. The blanket exception was over all patients."
-"if a client is paying for their methadone that's an indication they're working toward stability."
-patients were earning levels but have blanket exception.
-stopped adding to individual charts since the blanket exception covers the entire agency.
-"with the initial blanket exception we ran the approval out to 8/31/20-when it had just started. Now we get blanket exception for agency."
- "The blanket exceptions cover all intakes, active patients and discharges within the specified time frame. There is no requirement in regulation either state or federal we document which individual patients we apply the blanket except to,

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V 118	Continued From page 14 it would however be reflected in the individual patient records. Per our discussion it is individualized patient to patient as well as dosing to dosing episode based on patient presentation and evaluation of patient status and needs." Interview on 2/2/21 with PD and PS/RN revealed: -we have no specific documentation to show that the Medical Director, counselor or nurse had staffed or screened clients for appropriateness of blanket exception privilege. This deficiency is cross referenced in 10A 27G.3601 (V233) Scope for a Type A1 rule violation and must be corrected within 23 days.	V 118		
V 233	27G .3601 Outpt. Opiod Tx. - Scope 10A NCAC 27G .3601 SCOPE (a) An outpatient opioid treatment facility provides periodic services designed to offer the individual an opportunity to effect constructive changes in his lifestyle by using methadone or other medications approved for use in opioid treatment in conjunction with the provision of rehabilitation and medical services. (b) Methadone and other medications approved for use in opioid treatment are also tools in the detoxification and rehabilitation process of an opioid dependent individual. (c) For the purpose of detoxification, methadone and other medications approved for use in opioid treatment shall be administered in decreasing doses for a period not to exceed 180 days. (d) For individuals with a history of being physiologically addicted to an opioid drug for at least one year before admission to the service, methadone and other medications approved for use in opioid treatment may also be used in	V 233		

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V 233	Continued From page 15 maintenance treatment. In these cases, methadone and other medications approved for use in opioid treatment may be administered or dispensed in excess of 180 days and shall be administered in stable and clinically established dosage levels. This Rule is not met as evidenced by: Based on interviews and record review the facility management failed to provide services designed to affect constructive changes in the client's lifestyle by using methadone in conjunction with the provision of medical services for 5 of 5 audited current clients (Clients #1, #2, #3, #4, #5) and 1 of 1 audited former client (FC #6). The findings are: Cross Reference: 10A 27G .0209 Medication Requirements (V118). Based on record review and interviews, the facility failed to assure medication was administered by trained staff for 1 of 1 audited former client (FC #6), failed to administer medications on the written order of authorized person affecting 2 of 5 audited clients (Client #3 and Client #4) and 1 of 1 former client (FC #6) and the Licensee (Program Sponsor/Registered Nurse) failed to demonstrate competency for medication administration for 1 of 1 audited former client (FC #6). Cross Reference: 10A 27G .3604 (E-K) Outpt. Opioid - Operations (V238). Based on record reviews and interviews, the facility failed to ensure that during the first year of continuous treatment each client attended a minimum of two counseling sessions per month, and after the first year of treatment attended at least one	V 233		

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counseling session per month for 2 of 5 audited current clients (Clients #1, #5) and 1 of 1 former client (FC #6); failed to conduct a minimum of one random urine drug screen (UDS) each month for 1 of 1 audited former client (FC #6); failed to ensure that one drug test per 3 month period was observed for 5 of 5 audited current clients (Clients #1, #2, #3, #4, #5) and 1 of 1 audited former client (FC #6).

Review on 1/26/21 of voice mail left for surveyor on 1/26/21 from PS/RN revealed:
"I just wanted to reach out to you and have an additional conversation-[PD] asked if we had any more additional paperwork around [FC #6], a couple or 3 things after I got some advice just to reiterate that our tele medication policy prior to opening up had been reviewed and approved by DHSR [Division of Health Service Regulation]- they had already read it, looked over it and approved it prior to us opening the doors;
2- NC [North Carolina] nursing board is very clear that as long as it is within their scope of practice anything that can be done face to face can be done telemedicine with ancillary personnel actually performing the task- that's in their practice guidelines for nursing;
3-Three days prior to us administering medication to [FC #6] we did get a directive from [NC Governor] asking all the practice boards to open up the telemedicine rules- seeing how the nursing board already had done that, we felt that was justified.
The last thing I pointed out to the advice and consultation of a professional was that there is nowhere in the DHHS [Department of Health and Human Services] regulations that said we can't do it, in that sense, unless it was absence of a direct prohibited against whatever procedure then we fall back on our guidelines from our practice

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V 233	Continued From page 17 boards that says any nursing practice can be done via telemedicine ..." (unable to understand last few words). "I can document all this if you need it or I can send you the documentation that would clearly demonstrate our thought process on [FC #6] or I can email with all the attachments. Give me a call and let me know what you need ..." Review on 2/1/21 of the initial Plan of Protection submitted 2/1/21 and signed by the PS/RN revealed: "Our intent is to continue to ensure patient safety and satisfy the surveyor's directive that there a requirement of immediately completing this form upon receipt, we do intend to appeal the surveyor's conclusions in the appeals process. 10A NCAC 27G .3601 (V233) Scope - Type A1 Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. 10A NCAC 27G.3604 (V238) Operations - cross referenced into Type A1 Effective 2/1/21 all monthly drug screens shell continue to be observed. 10A NCAC 27G.0209 (V118) Medication Requirements- cross referenced into Type A1 Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. Describe your plans to make sure the above happens. 2/2/21 staff members shall be educated concerning the scope of the complaint and effective remedial action. This will be documented in and in service training record." Review on 2/2/21 of the 2nd Plan of Protection submitted 2/2/21 and signed by the PS/RN revealed: -"Our intent is to continue to ensure patient safety and follow through on the complaint to satisfy the	V 233		

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surveyor's directive that there a requirement of immediately completing this form upon receipt, we do intend to appeal the surveyor's conclusions in the appeals process.
10A NCAC 27G .3601 (V233) Scope - Type A1
Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. Medication administration by telenursing will not be allowed in any future dosing, all nursing staff will be trained accordingly.
10A NCAC 27G.3604 (V238) Operations - cross referenced into Type A1
Effective 2/1/21 all monthly drug screens shell continue to be observed. Compliance with UDSs shall be monitored in the Monthly Consolidated Requirements report in Methasoft. All counseling sessions shall be monitored in the Monthly Consolidated Requirements report in Methasoft. The Monthly Consolidate Requirements reports captures required UDS and counseling sessions based on documentation in the EHR [Electronic Health Record] record and shall be monitored by the Program Director. We have already contacted [national security service] and determined which video system to monitor UDSs in real time by nursing staff will be used and installed by 2/19/21.
10A NCAC 27G.0209 (V118) Medication Requirements- cross referenced into Type A1
Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. No dosing my telenursing shall be permitted in the future. The MD decided to not dose the patient on this particular Sunday. That was the MD's prerogative, no options were offered. In the future if there appears to be a lack of continuity in dosing by the MD the nurse will bring this to the MD's attention for clarification.
Documentation shall be made in the Dose Comment field on the patients dosing screen for Takeout medication covered by the blanket

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V 233	Continued From page 19 exception. 2/2/21 staff members shall be educated concerning the scope, of the complaint and effective remedial action. This will be documented in and in service training record. In service training will be conducted by the [PS/RN] who is a Registered Nurse." Review on 2/2/21 of 3rd Plan of Protection submitted 2/2/21 and signed by the PS/RN revealed: "Our intent is to continue to ensure patient safety and follow through on the complaint to satisfy the surveyor's directive that there a requirement of immediately completing this form upon receipt, we do intend to appeal the surveyor's conclusions in the appeals process. 10A NCAC 27G .3601 (V233) Scope - Type A1 Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. Medication administration by telenursing will not be allowed in any future dosing, all nursing staff will be trained accordingly. 10A NCAC 27G.3604 (V238) Operations - cross referenced into Type A1 Effective 2/1/21 all monthly drug screens shell continue to be observed. Compliance with UDSs shall be monitored in the Monthly Consolidated Requirements report in Methasoft. All counseling sessions shall be monitored in the Monthly Consolidated Requirements report in Methasoft. The Monthly Consolidate Requirements reports captures required UDS and counseling sessions based on documentation in the EHR record and shall be monitored by the Program Director. We have already contacted [national security service] and determined which video system to monitor UDSs in real time by nursing staff will be used and installed by 2/19/21. 10A NCAC 27G.0209 (V118) Medication	V 233		

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V 233	Continued From page 20 Requirements- cross referenced into Type A1 Effective 2/1/21 all medication shall continue to be supplied by a LPN or RN. No dosing my telenursing shall be permitted in the future. The MD decided to not dose the patient on this particular Sunday. That was the MD's prerogative, no options were offered. In the future if there appears to be a lack of continuity in dosing by the MD the nurse will bring this to the MD's attention for clarification. The number of COVID 19 take out exceptions staffed and assessed will be documented on the Patient List by Phase by Medical Director, nursing and counseling staff. Documentation for each patient's medication administration under the COVID 19 blanket exception shall be made in the Dose Comment field on the patient's dosing screen by the dosing nurse. 2/2/21 staff members shall be educated concerning the scope, of the complaint and effective remedial action. This will be documented in and in service training record. In service training will be conducted by the [PS/RN] who is a Registered Nurse." This facility provided outpatient services for clients with opioid use disorder, anxiety disorder, depression, arthritis, Afib, asthma and post traumatic stress disorder. On Friday April 10, 2020, FC #6 informed the facility that he had spilled/lost his remaining takeouts that he had received on 4/6/20. The Medical Director (MD) was notified and ordered the client to be dosed at 60% (120mg) for 3 days, 80% (160mg) for 2 days then back to his current dose of 200mg and reduced his Take Outs (TO) from Phase 3 to Phase 1 for 30 days. The order did not cover Sunday 4/12/20. Former Nurse #2 (who was only filling in) dosed FC #6 on Friday 4/10/20 at 8:56am and marked the MAR as "TO" (takeout).	V 233		

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V 233	Continued From page 21 FC #6 was taken to the local emergency room via ambulance on 4/10/20 at 3:42pm with chest pain, shortness of breath. He was discharged at 7:25pm with likely upper respiratory infection. On Saturday April 11, 2020, FC #6 was dosed by the PD at 120milligrams in the parking lot due to COVID exposure and was also marked as "TO". The PD is not licensed or qualified to dose methadone. FC #6 was not dosed on 4/12/20 nor was there documentation of alternatives offered such as a Take Out or referral to another clinic as guest doser. FC #6 continued to receive 23 total take outs from 4/13/20-5/11/20, despite MD order on 4/13/20 for Phase 1 for 30 days which would allow for 4 TOs (Sunday only). FC #6 received no counseling for 2 of his 5 months in service and only had 2 UDS collected during his 5 months at the clinic. SOTA also determined the PD may have inappropriately logged in under an alternative staff's credentials to perform dosing services in a non-emergency situation. Documentation showed that 100% of clients reviewed had UDS marked observed but were not actually observed only monitored outside the bathroom door. 50% of clients reviewed did not meet counseling requirements. The facility requested blanket exceptions each month for clients to have up to 28 TOs but provided no tracking or monitoring documentation. No documentation of screening by Medical Director along with counseling and nursing as indicated would be completed in facility's exception requests. This deficiency constitutes a Type A1 rule violation for serious neglect and must be corrected within 23 days. An administrative penalty of $3000.00 is imposed. If the violation is not corrected within 23 days, an additional administrative penalty of $500.00 per day will be	V 233		

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V 233	Continued From page 22 imposed for each day the facility is out of compliance beyond the 23rd day.	V 233		
V 238	27G .3604 (E-K) Outpt. Opiod - Operations 10A NCAC 27G .3604 OUTPATIENT OPIOD 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 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	V 238		

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V 238	Continued From page 23 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 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	V 238		

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V 238	Continued From page 24 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 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	V 238		

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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 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

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V 238	Continued From page 26 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 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.	V 238		

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This Rule is not met as evidenced by:
Based on record reviews and interviews, the facility failed to ensure that during the first year of continuous treatment each client attended a minimum of two counseling sessions per month, and after the first year of treatment attended at least one counseling session per month for 2 of 5 audited current clients (Clients #1, #5) and 1 of 1 former client (FC #6); failed to conduct a minimum of one random urine drug screen (UDS) each month for 1 of 1 audited former client (FC #6); failed to ensure that one drug test per 3 month period was observed for 5 of 5 audited current clients (Clients #1, #2, #3, #4, #5) and 1 of 1 audited former client (FC #6). The findings are:

Finding #1-failure to meet counseling requirements.

Record review on 1/7/21 for Client #1 revealed:
-Date of Admission: 11/5/20 with diagnoses of severe opioid use disorder, chronic right ankle pain and asthma.
-no counseling sessions were documented for November or December 2020.

Interview on 1/6/21 with Client # 1 revealed:
-had been there 3 months
-received 90 milligrams (mg) dose- felt stable
-only other medication was albuterol
-Saw his counselor daily usually but also had appointments
-UDS 1-2 times a month

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V 238	Continued From page 28 -Nurse #1 had been the only doser he's had or had seen dose. Record review on 1/8/21 for Client #5 revealed: -Date of admission 10/19/20 with diagnoses of opioid use disorder. -no counseling sessions were documented in December 2020. Interview on 1/6/21 with Client #5 revealed: -she started at the clinic 2nd or 3rd week in October -she takes pain medication for her feet -currently at 160mg - seems stable -had talked to counselor twice over the phone. Record review on 1/8/21 for FC #6 revealed: Date of admission 3/16/20 with diagnosis of opioid use disorder Date of discharge 8/3/20. -No counseling sessions for April or July 2020. The Program Director (PD) was listed as counselor during that time for FC #6. Finding #2-failure to meet monthly UDS requirements Record review on 1/8/21 for FC #6 revealed: Date of admission 3/16/20 with diagnosis of opioid use disorder Date of discharge 8/3/20. -2 UDS were conducted; 1- at intake on 3/16/20 (positive for cocaine) and on 5/11/20 (no methadone metabolite checked as present) both were checked as observed. -There was no UDS obtained for April, June or July 2020. Finding #3- failure to meet quarterly requirements for observed UDS.	V 238		

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V 238	Continued From page 29 Record review on 1/7/21 for Client #1 revealed: -Date of Admission: 11/5/20 with diagnoses of severe opioid use disorder, chronic right ankle pain and asthma. -Review of UDS revealed: -11/5/20 was positive for THC and fentanyl -12/4/20 was positive for fentanyl -12/22/20 was positive for fentanyl -1/8/21 was positive for fentanyl -All screens were also checked as observed although there were no additional comments that these were direct observations. Interview on 1/6/21 with Client # 1 revealed: -UDS 1-2 times a month - Counselor #2 would go into the bathroom with him for observed. -Nurse #1 had been the only doser he's had or had seen dose. Record review on 1/7/21 for Client #2 revealed: -Date of admission 12/23/20 with diagnosis of opioid use disorder. -Initial UDS taken on 12/23/20 revealed positives for amphetamine, benzodiazepine, opioids, oxycodone, fentanyl and buprenorphine and was checked as observed. - There were no additional comments that these were direct observations. Interview on 1/6/21 with Client #2 revealed: -had only been at clinic 2 weeks-was in previous treatment (out of state inpatient) and relapsed. -currently at 60mg- still going up 5mg daily. -UDS was not observed. Record review on 1/7/21 for Client #3 revealed: -Date of admission was 5/4/20 and readmitted 9/29/20 with diagnoses of opioid use disorder,	V 238		

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enlarged prostate, arthritis, Afib (Atrial Fibrillation), history of alcohol dependence.
-review of UDS revealed:
-9/29/20 positive for benzodiazepine was checked as observed.
-10/1/20 -(no illicit substances noted)
-11/11/20 positive for benzodiazepine was checked as observed.
-12/16/20 positive for benzodiazepine was checked as observed.
- There were no additional comments that these were direct observations.

Interview on 1/6/21 with Client #3 revealed:
-had been at clinic 5 months-did not transfer - in treatment then relapsed- been sober 356 days
-had used suboxone but didn't like it
-currently at 60mg and has 6 take homes
-UDS every 3 weeks-not observed

Record review on 1/8/21 for Client #4 revealed:
-Date of admission 4/7/20 with diagnoses of severe opioid use disorder, Post Traumatic Stress Disorder, anxiety and Depression.
-review of UDS revealed:
-8/19/20 was positive for amphetamines was checked as observed.
-9/4/20 was positive for benzodiazepine was checked as observed.
-10/8/20 was positive for amphetamines was checked as observed.
-11/11/20 was positive for amphetamines, oxycodone and fentanyl and was checked as observed.
-12/1/20 was positive for oxycodone and fentanyl and was checked as observed.
-There were no additional comments that these were direct observations.

Interview on 1/6/21 with Client #4 revealed:

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V 238	Continued From page 31 -began several months ago -current dose 160mg - no take homes -UDS monthly- front desk staff stood at door-never had anyone go in bathroom with her. Record review on 1/8/21 for Client #5 revealed: -Date of admission 10/19/20 with diagnoses of opioid use disorder. -review of UDS revealed: -10/19/20 was positive for amphetamine, benzodiazepine, oxycodone and was checked as observed. -11/4/20 was checked as observed. -12/1/20 was positive for benzodiazepine and opioids and was checked as observed. - There were no additional comments that these were direct observations. Interview on 1/6/21 with Client #5 revealed: -she started at the clinic 2nd or 3rd week in October. -she takes pain medication for her feet. -currently at 160mg - seemed stable. -UDS monthly- not observed-"no one goes in with you." Record review on 1/8/21 for FC #6 revealed: -Date of admission 3/16/20 with diagnosis of opioid use disorder. -Date of discharge 8/3/20. -2 UDS were conducted; - at intake on 3/16/20 (positive for cocaine) and on 5/11/20 (no methadone metabolite checked as present) both were checked as observed. No additional comments that these were direct observation. Interview on 1/6/21 with Counselor #1 revealed: -Had been there since September -was a registered CADC (Certified Alcohol Drug Counselor)	V 238		

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V 238	Continued From page 32 -the system randomly chose dates for UDS -"[Staff #1] and [Counselor #3] who work the front desk observe screens- don't know about males." Interview on 1/21/21 with Counselor #2 revealed: -started 8/15/20 -August to October - heavy on teleconference -his notes did not indicate if teleconference or face to face- would have to check time of note -never had any interaction with UDS collection. -he only saw results and entered into the system. -he "has never observed anyone-the front desk or medical handles that. They package and send thru [national carrier]." Interview on 1/6/21 with Nurse #1 revealed: -was a LPN (Licensed Practical Nurse) and was hired in May- worked 6 days a week from 5:30-11:30am and Saturday 7-9am -observed UDS meant she was standing outside bathroom- no handbags, purses, boxes into the restroom. If a client had a history of tampering then she would go into restroom with them for observation which she had done "maybe half dozen times." The new nurse would also observe. Interview on 1/6/21 with the PD revealed: -"Telecounseling was based on Governor's orders"- started in April and still an option. -don't recall having the counselors indicate if appointments with clients was face to face or telehealth. "Didn't think it mattered since they were not billing Medicaid." -previously had someone at sister facility doing QA (quality assurance)- checking UDS, counseling, etc. PD is now completing QA process to check requirements in check. -Observations- no jackets, purses, boxes, etc- have staff stand outside the door.	V 238		

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V 238	Continued From page 33 -"closely observed- a staff goes into the bathroom-would indicate this in comments- observed would be checked in the system-direct observation would be in comment box." -if no metabolite in UDS, would consider that as a positive screen because that was usually an indication of tampering or falsification. Interview on 1/28/21 with the Program Sponsor/Registered Nurse revealed: -"there is no definition of observation in the rules." -"this is in our policy" This deficiency is cross referenced in 10 A 27G .3601 (V233) Scope for a Type A1 rule violation and must be corrected within 23 days.	V 238		
V 367	27G .0604 Incident Reporting Requirements 10A NCAC 27G .0604 INCIDENT REPORTING REQUIREMENTS FOR CATEGORY A AND B PROVIDERS (a) Category A and B providers shall report all level II incidents, except deaths, that occur during the provision of billable services or while the consumer is on the providers premises or level III incidents and level II deaths involving the clients to whom the provider rendered any service within 90 days prior to the incident to the LME responsible for the catchment area where services are provided within 72 hours of becoming aware of the incident. The report shall be submitted on a form provided by the Secretary. The report may be submitted via mail, in person, facsimile or encrypted electronic means. The report shall include the following information: (1) reporting provider contact and identification information;	V 367		

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V 367	Continued From page 34 (2) client identification information; (3) type of incident; (4) description of incident; (5) status of the effort to determine the cause of the incident; and (6) other individuals or authorities notified or responding. (b) Category A and B providers shall explain any missing or incomplete information. The provider shall submit an updated report to all required report recipients by the end of the next business day whenever: (1) the provider has reason to believe that information provided in the report may be erroneous, misleading or otherwise unreliable; or (2) the provider obtains information required on the incident form that was previously unavailable. (c) Category A and B providers shall submit, upon request by the LME, other information obtained regarding the incident, including: (1) hospital records including confidential information; (2) reports by other authorities; and (3) the provider's response to the incident. (d) Category A and B providers shall send a copy of all level III incident reports to the Division of Mental Health, Developmental Disabilities and Substance Abuse Services within 72 hours of becoming aware of the incident. Category A providers shall send a copy of all level III incidents involving a client death to the Division of Health Service Regulation within 72 hours of becoming aware of the incident. In cases of client death within seven days of use of seclusion or restraint, the provider shall report the death immediately, as required by 10A NCAC 26C .0300 and 10A NCAC 27E .0104(e)(18). (e) Category A and B providers shall send a	V 367		

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V 367	Continued From page 35 report quarterly to the LME responsible for the catchment area where services are provided. The report shall be submitted on a form provided by the Secretary via electronic means and shall include summary information as follows: (1) medication errors that do not meet the definition of a level II or level III incident; (2) restrictive interventions that do not meet the definition of a level II or level III incident; (3) searches of a client or his living area; (4) seizures of client property or property in the possession of a client; (5) the total number of level II and level III incidents that occurred; and (6) a statement indicating that there have been no reportable incidents whenever no incidents have occurred during the quarter that meet any of the criteria as set forth in Paragraphs (a) and (d) of this Rule and Subparagraphs (1) through (4) of this Paragraph. This Rule is not met as evidenced by: Based on interview and record review, the facility failed to report a Level II incident to the Local Management Entity (LME) responsible for the catchment area where services were provided within 72 hours of becoming aware of the loss or spillage of medication and administration of replacement doses. The findings are: Record review on 1/8/21 for Former Client (FC) #6 revealed: -Date of admission 3/16/20 with diagnosis of	V 367		

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opioid use disorder
-Date of discharge 8/3/20.
-Review of doctor's orders revealed:
-4/10/20- "patient missing take homes- dosed at 120mg [milligrams] 4/10/20, 4/11/20, 14/13/20- signed 4/10/20"
-4/13/20- "dose at 160mg on 4/14/20, 4/15/20 and dose 200mg on 4/16/20- continue methadone 200mg qd [once daily] thereafter- phase down to level 1 for a minimum of 30 days" - signed 4/15/20
-Review of MAR (Medication Administration Record) revealed:
-4/6/20 dosed 200mg and given 6 TO (take outs) to cover from 4/7/20-4/12/20.
-4/10/20 dosed 120mg and marked as "TO"-Comments "Exception given D/T [due to] spilled doses. Order signed by MD [Medical Director]." Entered by Former Nurse #2.
-4/11/20 dosed 120mg and marked as "TO"-Comments "Pt [patient] reports takeouts spilled. Dose in house @120mg per MD order." Entered by Program Sponsor/Registered Nurse (PS/RN).
-4/12/20 patient absent.

Review on 1/5/21 of incident reports from 3/1/20-12/31/20 revealed:
-3/13/20- additional 5mg given to client in error- MD contacted.
-5/15/20-additional 30mg given to client in error- pt counseled, Narcan given to client to take with them and MD notified
-5/27/20- take home bottle seal leaked- given replacement and faulty bottle destroyed
There was no incident report completed regarding FC #6's loss of take home doses and administration of replacement doses for 4/10-4/15/20.

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V 367	Continued From page 37 Interview on 1/25/21 with Program Director (PD) revealed: -had a PRN nurse who filled in sometimes, not often in March/April. -she worked on 4/10/20 but not 4/11/20. -no clients were scheduled to come in on Sat 4/11/20 but "we still had to open". -FC #6 called the clinic- PD called the PS/RN and the PS/RN called the MD. He didn't remember the specifics about the situation because it was so long ago. -it was confusing as to who was going to document- the PS thought the PD was doing paperwork and the PD thought the PS/RN was doing the paperwork. -"I dosed FC #6 in the parking lot on 4/11/20"- he did not receive any TOs -"4/10 and 4/11/20 were not TOs as indicated on the MAR-they were marked incorrectly." -"I probably should have done an incident report-the whole thing was confusing-it just didn't get done."	V 367		
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	V 536		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL044-074	A. BUILDING: _____ B. WING _____	C 02/02/2021

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V 536	Continued From page 38 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 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	V 536		

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V 536	Continued From page 39	V 536		

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 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

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V 536	Continued From page 40	V 536		

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 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.

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V 536	Continued From page 41 This Rule is not met as evidenced by: Based on personnel record review and staff interviews, the facility failed to ensure that all staff completed training in alternatives to restrictive intervention prior to providing services for 1 of 5 sampled staff (Staff #1). The findings are: Record review on 1/25/21 for Staff #1 revealed: -She was hired 11/5/20 as front desk staff. -no training was completed for alternatives to restrictive intervention. Interview on 1/6/21 with Staff #1 revealed: -she helped out working the front desk a couple days a week -she'd check-in patients and give UDS (urine drug screen) supplies if they were selected. -she would also check the central registry and place in the EMR (electronic medical record) -if she suspected an patient was impaired she would alert the nurse and they would assess. -she never observed any UDS. Interview on with the Program Director revealed: -"[Staff #1] is not an employee of PRS(Pisgah Recovery Services). She is a 1099 and only works for us PRN (as needed). It is my understanding that a 1099 is not required to have NCI."	V 536		