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V 000	INITIAL COMMENTS An annual and follow up survey was completed on 7/16/18. Deficiencies were cited. This facility is licensed for the following survey category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. Facility Census is 407.	V 000		
V 105	27G .0201 (A) (1-7) Governing Body Policies 10A NCAC 27G .0201 GOVERNING BODY POLICIES (a) The governing body responsible for each facility or service shall develop and implement written policies for the following: (1) delegation of management authority for the operation of the facility and services; (2) criteria for admission; (3) criteria for discharge; (4) admission assessments, including: (A) who will perform the assessment; and (B) time frames for completing assessment. (5) client record management, including: (A) persons authorized to document; (B) transporting records; (C) safeguard of records against loss, tampering, defacement or use by unauthorized persons; (D) assurance of record accessibility to authorized users at all times; and (E) assurance of confidentiality of records. (6) screenings, which shall include: (A) an assessment of the individual's presenting problem or need; (B) an assessment of whether or not the facility can provide services to address the individual's needs; and (C) the disposition, including referrals and recommendations;	V 105		

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

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V 105	Continued From page 2 implemented. The findings are: Review on 7/11/18 of a policy and procedure titled: "Medical Oversight Plan of Action (revised 11.9.2017)" revealed the following documented: -"Case staffing details will be documented as they occur; therefore, both clinical and medical staff must have the Medical Care Staffing form available at all times to ensure any issues or needs will be staffed within a timely manner;" -"Criteria for staffing: After the induction period (1st 30 days): Clients should be staffed for 2 consecutive UDS(Urine Drug Screen) for BABs (Benzodiazepines, Barbiturates, or Alcohol) including last 2 induction phase with all subsequent follow-up staffing to be determined by the physician. Clients should be staffed for 3 consecutive positive UDS for all other substances with all subsequent follow-up staffing to be determined by the physician;" -"Case staffing Process: The counselor and nurse will discuss the clients case. The details of this meeting will be documented on the Medical Case Staffing form. Counselors will document the details of the case staffing in a 1940 electronic note. Nurses will document the details of the case staffing in a medical note. This information gathered will be staffed with a McLeod Center physician or PA(physician's assistant) within a timely manner and the doctor will document any follow up recommendations. The nurse will be responsible for ensuring that all doctors orders are followed and will place a copy of the Medical Case Staffing Form in the counselor's box to ensure appropriate follow-up and effective communication. The Medical Case Staffing form will be placed/maintained in the individual client record in the pharmacy file cabinet." Interview on 7/10/18 with substance abuse	V 105		

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V 105	Continued From page 3	V 105		

counselor (SAC) #2 revealed:
-staff cases with the facility physician when there are two positive UDS for BABs;
-three positive UDS of any drug need to be staffed with the facility physician;
-at the most recent treatment team meeting, discussed the policy for staffing cases;
-also recently, the Program Manager (PM) went through every counselor's caseload to ensure there were no cases that needed to be staffed with the facility physician and had not been staffed;
-none of his cases had slipped through the cracks as he used a spreadsheet.

Interview on 7/11/18 with SAC #3 revealed:
-there is a policy that changed since she has been here;
-when she first came to work here, staffed cases with the facility physician for 3-4 consecutive positive UDS;
-in November 2017, policy was changed to staff cases with facility physician for 3 positive UDS for any substances;
-staff cases with the facility physician during treatment team meetings;
-was not present at the most recent treatment team meeting.

Interview on 7/11/18 with SAC #4 revealed:
-have treatment team meeting with the facility physician;
-after induction period, if client has 2 positive UDS for BABs;
-if 3 positive UDS for anything, staff with the facility physician;
-usually, the facility physician will write an order to see client to try to determine reason for continued positive UDS;
-at the most recent treatment team, went over the

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V 105	Continued From page 4 policy in detail and told to be more watchful of this issue; -after the meeting, the PM told everyone to check their caseloads for any cases with consecutive positive UDS that needed to be staffed with the facility physician. Interview on 7/11/18 with the facility physician revealed: -after two positive UDS, will order increased frequency of UDS if only testing once a month; -after three positive UDS, supposed to staff cases with her; -clinical staff supposed to bring any concerning clients to her attention; -was aware of a recent case involving a death that was not staffed with her even though there were several positive consecutive UDS; -after the death review, went over the policy with the clinical staff again in detail; -mixing fentanyl and buprenorphine can place a client at risk for an overdose. Interview on 7/11/18 with the PM revealed: -been in his position for 6 months; -became aware on 6/22/18 of a client death that occurred on 6/21/18 on SAC#1's caseload; -SAC#1 was off work on that day (Friday) on 6/22/18; -completed a death review on 6/25/18 (Monday) when SAC #1 returned to work; -results of the death review revealed the case was not staffed with the facility physician according to policy; -had several consecutive positive UDS prior to death; -at a recent treatment team meeting on 6/26/18, went over the policy with staff; -have no documentation of the above from the meetings on 6/26/18, have no sign in sheet for	V 105		

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V 105	Continued From page 5 staff; -have no documentation of any other oversight plan, any corrective measures in place to address the issues of SAC#1 not staffing the case with the facility physician; -issue of not staffing the case with the physician was discussed with SAC#1 at the death review. This deficiency is cross referenced into 10A NCAC 27G .3601 Outpatient Opioid Treatment Scope V 233 for a Type A1 rule violation and must be corrected within 23 days.	V 105		
V 109	27G .0203 Privileging/Training Professionals 10A NCAC 27G .0203 COMPETENCIES OF QUALIFIED PROFESSIONALS AND ASSOCIATE PROFESSIONALS (a) There shall be no privileging requirements for qualified professionals or associate professionals. (b) Qualified professionals and associate professionals shall demonstrate knowledge, skills and abilities required by the population served. (c) At such time as a competency-based employment system is established by rulemaking, then qualified professionals and associate professionals shall demonstrate competence. (d) Competence shall be demonstrated by exhibiting core skills including: (1) technical knowledge; (2) cultural awareness; (3) analytical skills; (4) decision-making; (5) interpersonal skills; (6) communication skills; and (7) clinical skills. (e) Qualified professionals as specified in 10A NCAC 27G .0104 (18)(a) are deemed to have met the requirements of the competency-based	V 109		

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V 109	Continued From page 6 employment system in the State Plan for MH/DD/SAS. (f) The governing body for each facility shall develop and implement policies and procedures for the initiation of an individualized supervision plan upon hiring each associate professional. (g) The associate professional shall be supervised by a qualified professional with the population served for the period of time as specified in Rule .0104 of this Subchapter. This Rule is not met as evidenced by: Based on records review and interviews, the facility failed to ensure 1 of 5 substance abuse counselors (SAC#1) demonstrated competency for the population served. The findings are: Review on 7/10/18 of SAC#1's record revealed: -hire date of 12/7/15 with job title of substance abuse counselor; -Licensed Clinical Addiction Specialist Associate, Bachelor's Degree in Social Work and Master's Degree in Social Work; -documentation of completed trainings in the Nature of Addiction, Withdrawal Symptoms, Secondary Complications, Client Rights, Confidentiality, Crisis Prevention Intervention. Review on 7/11/18 of staff meeting documentation from 1/2018-7/2018 revealed documentation dated 2/21/18 and completed by the Program Manager (PM): "counselors should bring case staffings...Counselors, PA (physician assistant) Program Manager, Medical Doctor, a nurse...will be present."	V 109		

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V 109	Continued From page 7 Review on 7/10/18 of facility incident reports from 4/2018-7/2018 revealed an incident report dated 6/22/18 regarding Deceased Client #22 (DC#22) documented the following: "On 6.22.18 McLeod Center staff were notified by a fellow client that an active Charlotte MAT[Medication Assisted Treatment] program client had passed away on 6.21.18. McLeod Center is unaware of the cause of the client's death at this time. According to the Medical Examiner's office an autopsy will be completed..." Review on 7/11/18 of DC #22's record revealed: -admission date of 8/30/16 with a discharge date of 6/22/18; -diagnoses of Opioid Use Disorder Severe; -admission information documented heroin use 1-2 grams daily, sporadic cocaine and marijuana use, no chronic illnesses, no history of mental health issues, no history of suicidal ideation and self injurious behaviors, no history of overdose, no family history of substance abuse, unemployed, no prescription medications, supportive family; -treatment plan dated 8/30/17 documented goals of attend clinic daily to maintain abstinence from illicit drug use, pay off parking tickets to get his drivers license reinstated, apply for 1-2 new jobs per week seek employment; -treatment plan dated 8/30/17 documented staff strategies of provide education on relapse prevention, disease of addiction, identifying triggers for use, identifying healthy coping skills, identify positive reward of abstinence from illicit use, assist in developing budget to achieve financial stability, utilize solutions focused approach and motivational interviewing, assist in updating his resume, role model interviewing skills, provide support, encouragement and community resource referrals for employment,	V 109		

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V 109	Continued From page 8 empathetic listening and unconditional positive regards; -no take homes; -no prescription medications; -last physical exam completed on 8/30/17; -North Carolina controlled substance registry check completed 5/8/18 showed no open prescriptions. Review on 7/11/18 of DC#22's MARs from 1/2018-6/2018 revealed the following: -1/1/18 10mg of Buprenorphine (Bup), facility physician order 12/14/17; -1/2/18-3/22/18 10mg of Bup; -3/23/18 decrease from 10mg of Bup to 6mg of Bup ordered by facility physician due to reported drowsiness by DC#22; -3/24/18 until 6/19/18 6mg stable dose; -no show 6/20/18 and 6/21/18. Review on 7/11/18 of DC#22's clinical contacts documentation from 1/2018-6/2018 revealed the following dates of clinical contact and topics addressed: -1/22 positive UDS (urine drug screen), employment, triggers for use; -2/2 productive activities, illicit use, job status; -2/12 positive UDS, recovery, job classes, illicit use; -2/28 progress on set goals, productive activities, abstinence; -3/19 use of non-prescribed opiates, feelings about family members declining health, allergies, appropriate over the counter medications; -3/29 positive UDS, recovery, triggers for use, process of changing behaviors, safety concerns of continued illicit use; -4/24 utilize positive coping skills to abstain from use, daily routine and tasks, employment, stabilization;	V 109		

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-5/2 coping mechanisms and productive activities, illicit drug use;
-5/22 positive UDS, triggers for use, negative influences, guilt feelings over illicit use, awareness of actions need to take to remain sober, family issues, healthy coping skills;
-6/5 positive UDS, complete updated relapse prevention plan, triggers for use, coping skills, influence by others;
-6/13 recovery, overall well-being;
-6/21 attempted to contact DC#22 to no success.

Review on 7/11/18 of DC#22's UDS from 1/2018-6/2018 revealed the following results of illicit drug use:
-1/15 norfentanyl;
-2/5 norfentanyl;
-3/14 opiates, morphine;
-4/27 cocaine, fentanyl, norfentanyl, opiates, morphine;
-5/8 cocaine, fentanyl, norfentanyl, opiates, morphine;
-5/25 fentanyl, norfentanyl, opiates, morphine;
-5/30 fentanyl, norfentanyl, hydromorphone, morphine;
-6/6 fentanyl, norfentanyl, opiates, hydromorphone, morphine;
-6/13 THC (marijuana);
-6/15 fentanyl, opiates, morphine.

Further review on 7/11/18 of DC#22's record revealed no documentation the case was staffed with the facility physician after the three consecutive positive UDS on 1/15, 2/5 and 3/14.

Interview on 7/11/18 with SAC#1 revealed:
-have treatment team meetings with the facility physician;
-DC#22 "appeared to be doing well, very pleasant, never came in impaired...came in daily;"

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V 109	Continued From page 10 -was testing positive to fentanyl and opiates; -all the positive UDS were addressed in clinical sessions; -"it was not staffed with the doctor and it should have been;" -"he did not appear to be in distress;" -talked about coping skills and relapse prevention; -"the policy is 2 consecutive, you should staff, he had 5-6 positive, should have staffed with the doctor, we (DC#22 and SAC#1) worked together for 2 years;" -was present at the death review for DC#22 and the issue of the case not staffed with the physician was identified; -"when something happens we have to do things right away, then things die down and we don't pay attention." This deficiency is cross referenced into 10A NCAC 27G .3601 Outpatient Opioid Treatment Scope V 233 for a Type A1 rule violation and must be corrected within 23 days.	V 109		
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	V 233		

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V 233	Continued From page 11 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 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 records review and interviews, the facility failed to ensure 1 of 5 Substance Abuse Counselors (SAC#1) provided 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 affecting 1 of 2 deceased clients (DC#2). The findings are: Cross Reference: 10A NCAC 27G .0201 GOVERNING BODY POLICIES Based on records review and interviews, the facility failed to ensure policies and procedures for applicable standards of practice were implemented V105. Cross Reference: 10A NCAC 27G .0203 COMPETENCIES OF QUALIFIED PROFESSIONALS AND ASSOCIATE PROFESSIONALS Based on records review and	V 233		

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V 233	Continued From page 12 interviews, the facility failed to ensure 1 of 5 substance abuse counselors (SAC#1) demonstrated competency for the population served V109. Interview on 7/11/18 with the Director of Quality Assurance revealed: -issue of case not staffed with the facility physician was identified during the death review of DC (Deceased Client) #22's record; -the Program Manager is responsible to address the issue with corrective action measures and also maintain documentation of measures taken; -not aware there was no documentation of corrective actions taken to address this issue and no documented plan of oversight; -will be addressed with all staff and ensure all cases staffed per policy with oversight in place. Review on 7/13/18 of a Plan of Protection dated 7/13/18 and completed by the Director of Quality Assurance(QA) documented the following: -"Effective immediately, all positive urine drug screens will be printed daily by the Dominion Diagnostic Laboratory Collector and will be forwarded to the Front Office Coordinator. The Front Office Coordinator will place a nursing and counseling hold in the client's electronic health record to ensure that the urine drug screen is addressed in a timely manner, The session will be documented in the client's electronic health record within 24 hours. A staffing schedule has been implemented to ensure availability of physicians to review specific concerns and determine if changes in the clients' treatment are needed. In addition, the positive drug screen report (Client Results by Practitioner) will be reviewed by the Program Manager and Charge Nurse on a monthly basis to ensure that all positive urine drug screens have been addressed	V 233		

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V 233	Continued From page 13 with the clients and staffed with the Physician in accordance with the medical oversight protocol;" -"A new protocol has been implemented concerning all level III incidents. Any concerns identified during the peer review process will be addressed with the specific staff member or the entire staff within one business day. A plan of correction will be established by the Program Manager to correct future discrepancies and the documented plan will be forwarded to the Director of Quality Assurance within three business days for approval. The QA Department will follow up on all plans of correction during the internal chart review process. All staff will be trained on the new protocol on 7/13/18. The Charlotte MAT Program Manager will oversee the plan of protection." DC#22 was diagnosed with Opioid Use Disorder Severe, was a client of this facility for one year and ten months and received 6mg of Buprenorphine to address his opiate dependence. Ten of ten urinary drug screens from 1/2018-6/2018 were positive for illicit substances(opiates, fentanyl, norfentanyl, cocaine, morphine, hydromorphine and marijuana)`. Despite SAC#1 being aware of a facility protocol in place since 11/2017 to staff all client cases with 3 consecutive positive drug screens with the facility physician, the SAC#1 did not staff DC#22's case with the facility physician. This lack of competency and lack of implementation of the established facility protocol constitutes a Type A1 rule violation for serious neglect and must be corrected within 23 days. An administrative penalty of $3,000.00 is imposed. If the violation is not corrected within 23 days, an additional administrative penalty of $500.00 per day will be imposed for each day the facility is out of compliance.	V 233		

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	MHL0601210	A. BUILDING: _____ B. WING _____	R 07/16/2018

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V 235	Continued From page 14	V 235		
V 235	27G .3603 (A-C) Outpt. Opiod Tx. - Staff 10A NCAC 27G .3603 STAFF (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 records review and interviews, the facility failed to ensure the staff/client ratio of 1/50. The findings are: Review on 7/9/18 of the facility counselor/client roster divided by case load revealed the following case load totals per counselor:	V 235		

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V 235	Continued From page 15 -two caseloads totaled 51 each; -two caseloads totaled 52 each. Interview on 7/10/18 with substance abuse counselor #1 (SAC) revealed she had a caseload of 54-55 clients. Interview on 7/10/18 with SAC #2 revealed he had a caseload of 52 clients. Interview on 7/10/18 with SAC #5 revealed she had a caseload of 55 clients. Interview on 7/9/18 with the Program Manager revealed: -a total census of 407 clients; -have a counselor on maternity leave; -have a counselor who resigned recently; -in process of hiring more counselors.	V 235		
V 736	27G .0303(c) Facility and Grounds Maintenance 10A NCAC 27G .0303 LOCATION AND EXTERIOR REQUIREMENTS (c) Each facility and its grounds shall be maintained in a safe, clean, attractive and orderly manner and shall be kept free from offensive odor. This Rule is not met as evidenced by: Based on observations, records review and interviews, the facility was not maintained in a safe manner. The findings are: Review on 7/10/18 of the facility incident reports from 4/1/18-7/10/18 revealed documentation of altercations between clients in the parking lot on	V 736		

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V 736	Continued From page 16 6/11 and 6/13. Observations on 7/9/18 and 7/11/18 between 7:30am-8:30am of the parking lot revealed: -several people standing around in the parking lot talking and smoking; -other people in their cars with people standing by their cars talking; -people dosing and coming out and not leaving promptly. Interview on 7/9/18 with SAC#1 revealed: -no security in the parking lot; -lots of yelling in parking lot, recently developed anxiety about yelling; -aware of an altercation in the parking lot; -police officer supposed to be here over weekend but not there every weekend; -maintenance staff been doing some security; -feel there is a problem, need more security on parking lot. Interview on 7/10/18 with SAC #2 revealed: -"security our biggest issue;" -used to have security, a lot of the counselors are upset when no security. Interview on 7/9/18 with SAC#5 revealed: -clients get into altercations in parking lot; -had to call the police one week on three occasions for clients not leaving and yelling in parking lot; -wish had more security. Interview on 7/9/18 with client #1 revealed: -aware of some fight in the parking lot once; -have had someone offer to sell him drugs in the parking lot once. Interview on 7/9/18 with client #20 revealed:	V 736		

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V 736	Continued From page 17 -people like to linger in the parking lot; -causes a lot of drama. Interview on 7/11/18 with the maintenance staff revealed: -filled in as "security" a few times; -patrol parking lot and tell clients to move on once dosed; -last weekend some clients arguing in parking lot. Interview on 7/11/18 with the Program Manager revealed: -local police are supposed to be at the facility on Mondays and Thursdays from 6am-9am and Saturdays and Sundays from 6am-9am; -been some times on the weekends the police do not show up and there is not security in the parking lot; -talked to local police coordinator and discovered no police are signing for the extra work at the facility as there are other jobs that pay much more; -have discussed with Administration possibility of hiring private security if can't have consistent police presence; -had a meeting yesterday about the situation and waiting to hear response concerning hiring outside security for parking lot. Interview on 7/13/18 with Administrative staff revealed: -aware of issues with security in parking lot; -looking into hiring private security; -also in discussions with local police administration regarding increased police presence in the parking lot and surrounding areas; -looking at the flow of clients in and out of the clinic and how to address it in a way all clients and staff are safe;	V 736		

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V 736	Continued From page 18 -looking into other ways to increase safety and security.	V 736		
V 752	27G .0304(b)(4) Hot Water Temperatures 10A NCAC 27G .0304 FACILITY DESIGN AND EQUIPMENT (b) Safety: Each facility shall be designed, constructed and equipped in a manner that ensures the physical safety of clients, staff and visitors. (4) In areas of the facility where clients are exposed to hot water, the temperature of the water shall be maintained between 100-116 degrees Fahrenheit. This Rule is not met as evidenced by: Based on observations and interviews, the facility failed to ensure in areas where clients where exposed to hot water. The temperature was maintained between 100-116 degrees Fahrenheit. The findings are: Observation on 7/10/18 at 2:00pm revealed the hot water temperature in the sink of the lab was 128 degrees Fahrenheit. Interview on 7/10/18 with the Lab Technician revealed clients do wash their hands in the lab sink when she draws blood. Review on 7/10/18 of the facility incident reports from 4/1/18-7/10/18 revealed no documentation of any injuries as a result of the hot water temperature in the lab sink. Interview on 7/13/18 with the Administrative Staff revealed no knowledge of hot water temperature	V 752		

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V 752	Continued From page 19 in the lab sink.	V 752		