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Wednesday, November 23, 2016 - Initial Licensure Survey

**MEDICATION-ASSISTED TREATMENT -
OPIOID TREATMENT PROGRAM
INITIAL LICENSURE SURVEY
NOVEMBER 21-23, 2016**

**PROGRAM CENSUS: 786
SAMPLE SIZE: 16**

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure the duties of the administrator of implementation of program policies and procedures and governing body policy. Staff affected: five (5) of eight (8) personnel files reviewed. Staff identifiers: B, J, K, L and M. Findings include:

(a) Review of personnel files on 11/22/16 revealed no documented evidence of cardiopulmonary resuscitation training for Staff B, nursing supervisor; Staff J, lab technician; Staff K, licensed practical nurse; Staff L, medical director; and Staff M, pharmacist.

(b) Review of the program's policy on 11/21/16 titled "Training and Development," identifying number HR-172, effective date 09/01/15, revealed under subtitle "Orientation" that "All newly hired employees must complete the designated new employee orientation within two (2) weeks of beginning work. At a minimum, the facility Orientation Program will include the following topics: CPR."

(c) Interview on 11/22/16 at 10:15 a.m. with Staff E, clinic director, confirmed Staff B, J, K, L and M had no documented evidence of cardiopulmonary resuscitation training/certification.

(d) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to follow requirements per program policy for staff to have cardiopulmonary resuscitation certification does not meet the intent of the regulation to ensure the duties of the administrator of implementation of program policies and procedures and governing body policy.

Statement of Deficiency

(1) Based on observation and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure that during all hours of operation every opioid treatment program shall have present and on duty at the program at least one of the following actively-licensed

health care professionals: program physician, physician extender or registered nurse. Patients affected: all patients being served by the program. Findings include:

(a) Observation of the program on 11/22/16 between 5:20 a.m. and 6:00 a.m. revealed the program to be administering and dispensing medications to multiple patients during this time frame.

(b) Interview on 11/22/16 at 7:40 a.m. with Staff E, clinic director, confirmed that during the hours of 5:00 a.m. and 6:00 a.m. on 11/22/16, the program did not have a program physician, physician extender or registered nurse on site. This same interview further confirmed that patients were being "dosed" during this time frame.

(c) Observation of the program on 11/23/16 at 7:35 a.m. revealed multiple patients being provided dosing at the program. Continued observation during this time frame revealed there was no required professional staff at the program location, to include, at least one of the following actively-licensed health care professionals: program physician, physician extender or registered nurse.

(d) Interview on 11/23/16 at 7:35 a.m. with Staff E, clinic director, confirmed that the program was dosing without the required actively licensed professional staff members.

(e) Interview on 11/23/16 at 7:50 a.m. with Staff E, clinic director, confirmed that the program would be open on 11/24/16 and that the program would not have a program physician, physician extender or registered nurse during the hours of operation (dosing) on that day.

(f) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure a qualified person during all hours of operation does not meet the intent of the regulation to ensure that during all hours of operation every opioid treatment program shall have present and on duty at the program at least one of the following actively-licensed health care professionals: program physician, physician extender or registered nurse.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment- Opioid Treatment Program failed to ensure that policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program. Patients affected: all patients served by the program. Findings include:

(a) Review of the policy and procedure manual provided by the program revealed no policy and procedure related to established ratios of primary counselors to patients served.

(b) Interview on 11/21/16 at 12:30 p.m. with Staff G, clinical supervisor, confirmed that the program does not have a policy or procedure to establish ratios of counselors to patients.

(c) Review of the "Patient List by Counselor" revealed each counselor was assigned to more than 50 patients. The counselor identifier and number of assigned patients as of 11/21/16, was as follows:

- (i) Staff W - 56 patients assigned;**
- (ii) Staff D - 55 patients assigned;**
- (iii) Staff V - 66 patients assigned;**
- (iv) Staff U - 53 patients assigned;**
- (v) Staff T - 69 patients assigned;**
- (vi) Staff I - 63 patients assigned;**
- (vii) Staff X - 60 patients assigned;**
- (viii) Staff H - 61 patients assigned;**
- (ix) Staff Q - 58 patients assigned;**
- (x) Staff Y - 57 patients assigned;**
- (xi) Staff O - 60 patients assigned;**
- (xii) Staff R - 67 patients assigned; and**
- (xiii) Staff Z - 60 patients assigned.**

(d) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to establish ratios of counselors to patients and to ensure that each counselor has no more than 50 patients does not meet the intent of the regulation to ensure that policies and procedures shall establish ratios of primary counselors to persons served that are adequate to allow sessions to occur as mandated and that will allow persons served access to a primary counselor, either on site or by referral, but there shall be at least one counselor for every 50 patients in the program.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure that newly employed counselors and other non-physician clinical staff without experience in a recovery-based opioid treatment program shall receive initial training lasting at least 20 hours and consist of, at a minimum, the following: substance use disorder overview; opioid treatment, detoxification protocols, recovery models, basic pharmacology and dosing; characteristics of the substance use disorder population; drug screening and observation of sample collection; program policy and procedure; confrontation, de-escalation and anger management; cultural sensitivity as necessary and appropriate; current strategies for identifying and treating alcohol, cocaine and other substance use disorders; identification of co-occurring behavioral health or development disorders; and other clinical issues as appropriate for the population served. Staff affected: four (4) of eight (8) personnel files reviewed. Staff identifiers: Staff B, I, J and K. Findings include:

(a) Review on 11/22/16 of employee records revealed no documented evidence of training for Staff B, nursing supervisor, Staff I, counselor, Staff J, lab technician, and Staff K, licensed practical nurse.

(b) Interview on 11/22/16 at 10:15 am with Staff E, clinic director, confirmed Staff B, I, J, and K had no documented evidence of training.

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to document 20 hours of required training for staff, does not meet the intent of the regulation to ensure that newly employed counselors and other non-physician clinical staff without experience in recovery-based opioid treatment program shall receive initial training lasting at least 20 hours and consist of, at a minimum, the following: substance use disorder overview; opioid treatment, detoxification protocols, recovery models and basic pharmacology and dosing; characteristics of the substance use disorder population; drug screening and observation of sample collection; program policy and procedure; confrontation, de-escalation and anger management; cultural sensitivity as necessary and appropriate; current strategies for identifying and treating alcohol, cocaine and other substance use disorders, identification of co-occurring behavioral health or development disorders; and other clinical issues as appropriate for the population served.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to have an advisory council comprised of a designated group of no fewer than three individuals to serve in a non-managerial advisory capacity to the administrator and governing body. Patients affected: all patients served by the program. Findings include:

(a) Review of the CTC Division Operations Manual, pages 36-38, revealed no documented evidence of an advisory council.

(b) Interview on 11/21/16 at 10:50 a.m. with Staff G, clinical supervisor, confirmed the opioid treatment center does not have an advisory council.

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to have an advisory council does not meet the intent of the regulation that each opioid treatment center program shall have an advisory council comprised to a designated group of no fewer than three individuals to serve in a non-managerial advisory capacity to the administrator and governing body. The advisory council shall consist of individuals served by the program, at least one staff representative and interested community representatives or advocates.

Statement of Deficiency

(1) Based on observation and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure clean, safe and well-maintained patient and staff areas. Patients affected: all patients served by the program during the medication dosing observation. Patient identifiers: #5, #8, #11, #12, #15 and #16. Findings include:

- (a) Observation on 11/21/16 between 6:00 a.m. and 6:13 a.m. revealed Staff C, licensed practical nurse, working at dosing window one accepting used medicine bottles, cash, administering and dispensing, and labeling medications to Patient #11, #12 and #15 without wearing gloves, washing hands or using hand sanitizer at any time.**
- (b) Observation on 11/21/16 between 6:00 a.m. and 6:47 a.m. revealed Staff C, licensed practical nurse, working at dosing window one reaching into two open containers and placing medicine bottles and lids on countertop without using gloves or cleaning the counter.**
- (c) Observation on 11/21/16 between 6:48 a.m. and 6:55 a.m. revealed Staff A, physician assistant, working at dosing window three accepting used medicine bottles, cash, and administering medication to Patient #5, #8 and #16 without wearing gloves, washing hands or using hand sanitizer at any time.**
- (d) Observation during the course of the survey, 11/21/16 at 5:25 a.m. through 11/23/16 at 8:15 a.m., revealed an area of uneven and weak flooring covered by stained carpeting in the hallway adjacent to the patient bathroom causing a potential trip and fall hazard.**
- (e) Observation during the course of the survey, 11/21/16 at 5:25 a.m. through 11/23/16 at 8:15 a.m., revealed stained and frayed areas on the carpet throughout the building causing a potential trip and fall hazard.**
- (f) Observation on 11/22/16 at 11:50 a.m. revealed Staff O, counselor, performing a urine dipstick test without wearing gloves prior to or during the procedure.**
- (g) Interview on 11/22/16 at 12:20 p.m. with Staff O, counselor, confirmed that although gloves were available, she did not choose to use gloves because "they just don't fit my hands."**
- (h) Observation during the course of the survey, 11/21/16 at 5:25 a.m. through 11/23/16 at 8:15 a.m., revealed a variety of used toys scattered in various waiting rooms and conference rooms throughout the building.**
- (i) Interview on 11/23/16 at 7:35 a.m. with Staff H, clinic director, confirmed that most of the toys are donated for the patients and public use and are disinfected daily, although no staff was assigned the task, "everyone does it, I even do it or I tell the housekeeper and he does it."**
- (j) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure a clean, safe and well-maintained environment for patients and staff does not meet the intent of the regulation that each opioid treatment program facility shall have clean, safe, and well-maintained patient and staff areas.**

Statement of Deficiency

(1) Based on observation and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure sanitary and secure dosing areas. Patients affected: all patients served by the program. Patient identifier: #5, #6, #8, #11, #12, #15 and #16. Findings include:

(a) Observation on 11/21/16 between 6:00 a.m. and 6:13 a.m. revealed Staff C, licensed practical nurse, working at dosing window one accepting used medicine bottles, cash, administering and dispensing, and labeling medications to Patient's #11, #12, and #15 without wearing gloves, washing hands or using hand sanitizer at any time.

(b) Observation on 11/21/16 between 6:00 a.m. and 6:47 a.m. revealed Staff C, licensed practical nurse, working at dosing window one reaching into two open containers and placing medicine bottles and lids on countertop without using gloves or cleaning the counter.

(c) Observation on 11/21/16 at 6:10 a.m. revealed patient #11 approaching dosing window one for medication administration without removing his hat. Staff C, licensed practical nurse, did not ask him to remove it for proper identification.

(d) Observation on 11/22/16 at 11:45 a.m. revealed a patient approaching dosing window one for medication administration wearing a toboggan hat with a hoodie pulled over it. Staff K, licensed practical nurse, did not ask him to remove them for proper identification.

(e) Observation on 11/22/16 at 12:30 revealed two signs posted at the entrance of the line for medication administration dosing windows that stated "Don't forget ...NO HATS ON at window."

(f) Observation on 11/21/16 between 6:48 a.m. and 6:55 a.m. revealed Staff A, physician assistant, working at dosing window three accepting used medicine bottles, cash, and administering medication to Patient's #5, #8, and #16 without wearing gloves, washing hands or using hand sanitizer at any time.

(g) Observation on 11/21/16 at 6:55 a.m. revealed the door to the private dosing area was unlocked as surveyor exited and did not automatically lock when shut.

(h) Interview on 11/22/16 at 6:55 a.m. with Staff A, physician assistant, confirmed the door was supposed to be locked at all times, yet at this time it was not. She was then observed reaching into the room to lock the door manually.

(i) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to maintain sanitary conditions during medication administration and the failure to secure dosing areas and ensure proper identification for security does not meet the intent of the regulation that each Medication-Assisted Treatment-Opioid Treatment Program facility shall have sanitary, secure, and private dosing areas.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to be responsible for ensuring that staff and contractors comply with all provisions of this rule. All clinical staff members and volunteers shall complete initial and continuing education and training that is specific to their job function, their interactions with patients, the pharmacotherapies to be used at the program, and patient populations to be served. Staff affected: six (6) of eight (8) personnel files reviewed. Staff identifiers: B, H, I, J, K and M. Findings include:

(a) Review on 11/22/16 of personnel records revealed no documented evidence of orientation or continuing education for Staff B, nursing supervisor; Staff I, counselor; Staff K, licensed practical nurse; and Staff M, pharmacist.

(b) Review of the program's facility on 11/21/16 revealed a policy titled "Training and Development" identifying number HR-172, effective date 09/01/15 revealing a list of topics to be covered during orientation and "In-Service Education and Mandatory Meetings."

(c) Review on 11/21/16 and 11/22/16 of personnel records revealed that Staff B, nursing supervisor, Staff H, the medicare therapist, Staff I, counselor, Staff J, lab technician, Staff K, licensed practical nurse, and Staff M, pharmacist, were not following policy titled "Training and Development" identifying number HR-172.

(d) Interview on 11/22/16 at 10:15 a.m. with Staff E, clinic director, confirmed Staff B, I, K and M had no documented evidence of orientation or continuing education in personnel files.

(e) Review on 11/21/16 and 11/22/16 of personnel records revealed a document named "HR Specific Policy Training-1.19.2016" that has 65 policy names with staff members' signatures beside each policy.

(f) Interview on 11/22/16 at 6:50 a.m. with Staff G, clinical supervisor, confirmed that staff who signed document "HR Specific Policy Training-1.19.2016" demonstrates that staff understand the policies and can demonstrate them.

(g) Interview on 11/22/16 at 7:00 a.m. with Staff J, lab technician, confirmed "I read these policies when I first started a year ago. I am sure I can't demonstrate them." Staff further stated she did not remember attending the training on 01/19/16. Further interview with Staff J did not demonstrate that she knew where to find the policy manual.

(h) Interview on 11/22/16 at 7:35 a.m. with Staff H, therapeutic recreational therapist, confirmed "She understands policies, but cannot demonstrate them." Further interview with Staff H did not demonstrate that she knew where to find the policy manual.

(i) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure orientation, continuing education, and adequate understanding of training for all staff members does not meet the intent of the regulation to be responsible for ensuring that staff and contractors comply with all provisions of this rule. All clinical staff members and volunteers shall complete initial and continuing education and training that is specific to their job function,

their interactions with patients, the pharmacotherapies to be used at the program, and patient populations to be served.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to maintain confidential individual personnel files for every clinical staff member or volunteer, that shall contain, at a minimum: identifying information and emergency contacts. Staff affected: two (2) of eight (8) personnel files reviewed. Staff identifiers: B and L. Findings include:

(a) Review on 11/22/16 of personnel files revealed that Staff B, nursing supervisor, had no documented evidence of emergency contacts.

(b) Review on 11/22/16 of personnel files revealed that Staff L, medical director, had no documented evidence of identifying information.

(c) Interview on 11/22/16 at 10:15 a.m. with Staff E, clinic director, confirmed Staff B, nursing supervisor, had no documented emergency contacts and Staff L, medical director, had no documented identifying information in their personnel files.

(d) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to maintain emergency contacts and identifying information in personnel files does not meet the intent of the regulation to maintain confidential individual personnel files for every clinical staff member or volunteer, that shall contain, at a minimum identifying information and emergency contacts.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to maintain confidential individual personnel files for every clinical staff member or volunteer, that shall contain, at a minimum documentation of all licenses, certifications or other credentials. Staff affected: one (1) of eight (8) personnel files reviewed. Staff identifier: I. Findings include:

(a) Review on 11/22/16 of the personnel file of Staff I, counselor, revealed no documented evidence of certifications or other credentials.

(b) Interview on 11/22/16 at 10:15 a.m. with Staff E, clinic director, confirmed Staff I had no documented evidence of certifications or other credentials.

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to maintain evidence of certifications or other credentials does not meet the intent of the regulation to maintain confidential individual personnel files for every clinical staff member or volunteer, that shall contain, at a minimum documentation of all licenses, certifications or other credentials.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program (MAT) failed to develop, implement and maintain current quality assurance and quality control plans that include provision for the reduction or elimination of the patient's use of illicit opioids, illicit drugs and the problematic use of licit drugs; reduction or elimination of associated criminal activity; reduction or elimination of associated criminal activities; reduction of patient's behaviors contributing to the spread of infectious diseases; improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and assessment of medication-related issues, including but not limited to, take-home procedures, security, inventory and dosage issue. Patients affected: all patients served by the program. Findings include:

(a) Review of the CTC Division, Operations Manual, pages 48-50, revealed no documented evidence of the MAT program including provisions that address the reduction or elimination of the patient's use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reduction or elimination of associated criminal activity; reduction or elimination of associated criminal activities; reduction of patient's behaviors contributing to the spread of infectious diseases; improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and assessment of medication-related issues, including but not limited to, take-home procedures, security, inventory, and dosage issue as part of their current quality assurance and quality control plans.

(b) Interview on 11/21/16 at 12:10 p.m. with Staff G, clinical supervisor, confirmed no documented evidence of the MAT program including provisions that address the reduction or elimination of the patient's use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reduction or elimination of associated criminal activity; reduction or elimination of associated criminal activities; reduction of patient's behaviors contributing to the spread of infectious diseases; improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and assessment of medication-related issues, including but not limited to, take-home procedures, security, inventory, and dosage issue as part of their current quality assurance and quality control plans.

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program (MAT) to ensure the quality assurance and quality control plans included provisions that address the reduction or elimination of the patient's use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reduction or elimination of associated criminal activity; reduction or

elimination of associated criminal activities; reduction of patient's behaviors contributing to the spread of infectious diseases; improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and assessment of medication-related issues, including but not limited to, take-home procedures, security, inventory, and dosage issue does not meet the intent of the regulation that each MAT program shall develop, implement and maintain current quality assurance and quality control plans that include provision for the reduction or elimination of the patient's use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reduction or elimination of associated criminal activity; reduction or elimination of associated criminal activities; reduction of patient's behaviors contributing to the spread of infectious diseases; improvement of quality of life through the restoration of physical and behavioral health and functional status, including employment or volunteerism, as may be appropriate; and assessment of medication-related issues, including but not limited to, take-home procedures, security, inventory and dosage issue.

Statement of Deficiency

(1) Based on observation and documentation review, the Medication-Assisted Treatment-Opioid Treatment Program failed to ensure all patient records shall be kept confidential in accordance with all applicable federal and state requirements. Patient affected: one of one patient records exposed. Findings include:

(a) Observation on 11/21/16 at 3:15 p.m. of a confidential patient document titled "Dose Evaluation" sitting alone and unattended in a lobby chair with individuals present in the building with unauthorized clearance to read confidential patient records.

(b) Review of policy on 11/21/16 titled "Confidentiality-Release of Information," policy number HR-225, dated 09/01/15 reveals that patient information is to be kept confidential at all times.

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to keep patient records confidential, does not meet the intent of the regulation to ensure all patient records shall be kept confidential in accordance with all applicable federal and state requirements.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment -Opioid Treatment Program failed to ensure that the results of the multiple-program check shall be contained in the clinical record of the patient chart and the individualized treatment plan of care. Patients affected: nine (9) of nine (9) active patients in the sample. Patient identifiers #1 through #9. Findings include:

(a) Review of the clinical records for Patient #1 through #9 revealed a signed form for the multiple-program registration check to be completed.

(b) Continued review of the clinical records for Patient #1 through #9 revealed no results for any other programs being contacted. There were no responses from any other program contained within any of the nine (9) clinical records reviewed.

(c) Interview on 11/23/16 at 9:05 a.m. with Staff E, clinic director, and Staff G, clinical supervisor, confirmed that the multi-program check results were not in the clinical records of Patient #1 through #9.

(d) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure that the results of the multi-program checks are maintained in the clinical records does not meet the intent of the regulation to ensure that the results of the multiple-program check shall be contained in the clinical record of the patient chart and the individualized treatment plan of care.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to maintain the results from the Controlled Substance Monitoring Program database with the patient records. Patients affected: seven (7) of nine (9) active patients in the sample. Patient identifier: #1, #2, #3, #4, #6, #7 and #8. Findings include:

(a) Review of medical record for patient #1, admission date 09/01/16, revealed no documented evidence of the results from the Controlled Substance Monitoring Program database for the patient's intake, before the administration of medication-assisted treatment medication or other treatment in a MAT (Medication-Assisted Treatment) program or after the initial 30 days of treatment.

(b) Review of medical record for patient #2, admission date 10/13/16, revealed no documented evidence of the results from the Controlled Substance Monitoring Program database for the patient's intake, before the administration of medication-assisted treatment medication or other treatment in a MAT program or after the initial 30 days of treatment.

(c) Review of medical record for patient #3, admission date 04/15/16, revealed no documented evidence of results from the Controlled Substance Monitoring Program database for the dates of 04/16/16, 05/23/16, 06/25/16, 07/24/16 and 10/06/16. On these dates, documented evidence revealed a positive drug test.

(d) Review of medical record for patient #4, admission date 06/17/16, revealed no documented evidence of results from the Controlled Substance Monitoring Program database after the initial 30 days of treatment or at each 90-day treatment review.

(e) Review of medical record for patient #6, admission date 07/17/04, revealed only one (1) documented evidence of results from the Controlled Substance Monitoring Program database dated 06/25/16.

(f) Review of medical record for patient #7, admission date 03/28/16, revealed no documented evidence of results from the Controlled Substance Monitoring Program database after the initial 30 days of treatment or at each 90-day treatment review.

(g) Review of medical record for patient #8, admission date 06/30/16, revealed no documented evidence of results from the Controlled Substance Monitoring Program database after the initial 30 days of treatment or at each 90-day treatment review.

(h) Interview on 11/22/16 at 7:40 a.m. with Staff E, clinic director, confirmed missing documented evidence of results from the Controlled Substance Monitoring Program database from patient's #1, #2, #3, #4, #6, #7, and #8 medical records. She stated "We have the tabs in the charts and if you don't see them, they aren't there."

(i) Interview on 11/22/16 at 10:24 a.m. with Staff N, clinic supervisor, confirmed no documented evidence of results from the Controlled Substance Monitoring Program database after the initial 30 days of treatment or at each 90-day treatment review for patient #8.

(j) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to maintain the results from the Controlled Substance Monitoring Program database with the patient records at the patient's intake, before the administration of medication-assisted treatment medications or treatment in a MAT program, after the initial 30 days of treatment, after any positive drug test, and at each 90 day treatment review does not meet the intent of the regulation that the program physician shall access the Controlled Substance Monitoring Program database in order to ensure that the patient is not seeking prescription medication from multiple sources. The results obtained from the database shall be maintained with the patient records.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to develop a more comprehensive individualized treatment plan of care within 30 days after admission of a patient and have the document attached to the patient's chart no later than five days after the plan is developed. Patients affected: seven (7) of nine (9) active patients in the sample. Patient identifiers: #2, #3, #4, #5, #6, #7 and #8. Findings include:

(a) Review of Patient #2, #3, #4, #5, #6, #7 and #8 medical records revealed no documented evidence of a comprehensive individualized treatment plan of care being developed within 30 days after admission and being attached to the patient's chart no later than five days after the plan is developed.

(b) Interview on 11/22/16 at 7:40 a.m. with Staff E, clinic director, confirmed missing documentation from Patient #2, #3, #4,#5, #6, #7 and #8 medical record. She stated, "We have the tabs in the charts and if you don't see them, they aren't there."

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure that a comprehensive individualized treatment plan of care was developed within 30 days after admission and was attached to the patient's chart does not meet the intent of the regulation that within 30 days after admission of a patient, the MAT (Medication-Assisted Treatment) program shall develop a more comprehensive individualized treatment plan of care and attach it to the patient's chart no later than five days after the plan is developed. The individualized treatment plan of care shall be developed pursuant to the guidelines and protocols established by the American Society of Addiction Medicine (ASAM), the Center for Substance Abuse Treatment (CSAT) and the National Institute on Drug Abuse (NIDA), the American Association for the Treatment of Opioid Dependency (AATOD), or such other nationally recognized authority approved by the secretary. The individualized treatment plan or care shall include a recovery model based upon the approved guidelines and protocols.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to develop a more comprehensive individualized treatment plan of care within 30 days after admission of a patient and have the document attached to the patient's chart no later than five days after the plan is developed. Patients affected: seven (7) of nine (9) active patients in the sample. Patient identifiers: #2, #3, #4, #5, #6, #7 and #8. Findings include:

(a) Review of Patient #2, #3, #4, #5, #6, #7 and #8 medical records revealed no documented evidence of a comprehensive individualized treatment plan of care being developed within 30 days after admission and being attached to the patient's chart no later than five days after the plan is developed.

(b) Interview on 11/22/16 at 7:40 a.m. with Staff E, clinic director, confirmed missing documentation from Patient #2, #3, #4,#5, #6, #7 and #8 medical record. She stated, "We have the tabs in the charts and if you don't see them, they aren't there."

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure that a comprehensive individualized treatment plan of care was developed within 30 days after admission and was attached to the patient's chart does not meet the intent of the regulation that within 30 days after admission of a patient, the MAT (Medication-Assisted Treatment) program shall develop a more comprehensive individualized treatment plan of care and attach it to the patient's chart no later than five days after the plan is developed. The individualized treatment plan of care shall be developed pursuant to the guidelines and protocols established by the American Society of Addiction Medicine (ASAM), the Center for Substance Abuse Treatment (CSAT) and the National Institute on Drug Abuse (NIDA), the American Association for the Treatment of Opioid Dependency (AATOD), or such other nationally recognized authority approved by the secretary. The individualized treatment plan or care shall include a recovery model based upon the approved guidelines and protocols.

Statement of Deficiency

(1) Based on documentation review and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to have an individualized treatment plan of care that are reviewed by the program physician, primary counselor, and patient at least every 90 days and documented in the patient record. Patients affected: six (6) of nine (9) active patients in the sample. Patient identifiers: #3, #4, #5, #6 , #7 and #8. Findings include:

(a) Review of the records for Patient #3, #4, #5, #6, #7 and #8 revealed no documented evidence of an individualized treatment plan of care at least every 90 days.

(b) Interview on 11/22/16 at 7:40 a.m. with Staff E, clinic director, confirmed the missing documentation from Patient #3, #4, #5, #6, #7 and #8's medical record. She stated, "We have the tabs in the charts and if you don't see them, they aren't there."

(c) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure that an individualized treatment plan of care is documented in the patient record at least every 90 days does not meet the intent of the regulation that the individualized treatment plan of care shall be reviewed by the program physician, primary counselor, and patient at least every 90 days and documented in the patient record. Reviews shall address each of the objectives identified on the initial plan of care; document all treatment, counseling, medications and other services rendered to the patient; and document the patient's progress. A revised plan of care may be implemented with each review. If a new plan of care is not implemented, the reasons for such decision should be documented in the patient's record. Paper and electronic plans of care, including all reviews and updates must be acknowledged by the patient.

Statement of Deficiency

(1) Based on observation and interview, the Medication-Assisted Treatment-Opioid Treatment Program failed to observe all patient drug testing when using urine as a screening mechanism in order to minimize the chance of adulterating or substituting another individual's urine. Patients affected: all patients served by the program. Patient identifier: #5. Findings include:

(a) Observation on 11/21/16 at 6:23 a.m. revealed a patient supplying a urine sample on the monitor mounted at the ceiling between dosing window one and dosing window three in the medication room. Staff C, licensed practical nurse, was administering medication at dosing window one and Staff A, physician assistant, was administering medication at dosing window three, neither of whom was noted to look at the monitor.

(b) Observation on 11/21/16 at 6:48 a.m. revealed Staff A, physician assistant, instructing Patient #5 to supply urine sample prior to administering medication. Patient #5 given paperwork and sent to the lab. Patient #5 observed on monitor at ceiling between dosing window one and dosing window three supplying a urine sample. Staff A, physician assistant, continued to administer medication to patients and did not look at the monitor. Staff C, licensed

practical nurse, was administering medication at dosing window one and did not look at monitor.

(c) Interview 11/22/16 at 12:40 p.m. with Staff O, counselor, confirmed that if a urine drug test is ordered for a specific patient for a specific reason, staff will accompany patient to directly observe the patient urinating. All random drug tests are witnessed by the medical staff via monitor. The only monitor is in the medication room mounted at the ceiling between dosing window one and dosing window three and it does not record.

(d) The failure of the Medication-Assisted Treatment-Opioid Treatment Program to ensure that all patients will be observed when drug testing urine as a screening mechanism does not meet the intent of the regulation that when using urine as a screening mechanism, all patient drug testing shall be observed to minimize the chance of adulterating or substituting another individual's urine.