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Statement of Deficiency

**OPIOID TREATMENT PROGRAM - MEDICATION-ASSISTED TREATMENT
INITIAL LICENSURE SURVEY
MARCH 20-24, 2017**

**PROGRAM CENSUS: 358
SAMPLE SIZE: 20**

Statement of Deficiency

Based on observation and interview the program failed to ensure 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 professional: program physician, physician extender, or registered nurse. Findings include:

a. The Patient Handbook, page 1 was provided by the Clinic Director on 03/21/17. This page contained documentation of the "Dosing Hours" of the program were listed as follows:

Monday Friday (Priority Card), 5:00 a.m. to 6:00 a.m.

Monday, Tuesday, Thursday, Friday 6:00 a.m. to 2:00 p.m.

Wednesday 6:00 a.m. to 11:30 a.m.

Weekend (Saturday & Sunday) 6:00 a.m. to 8:00 a.m.

Holidays 6:00 a.m. 8:00 a.m.

b. Staff A, Program Physician ' s hours were provided by Staff I, Nursing Supervisor on 03/24/17. Interview with Staff I, Nursing Supervisor on 03/24/17 at 9:28 a.m. confirmed Staff A ' s hours were as follows:

02/02/17 (Thursday) 6:00 a.m. to 12:00 noon

02/06/17 (Monday) 6:00 a.m. to 12:00 noon

02/07/17 (Tuesday) 6:00 a.m. to 12:30 p.m.

02/09/17 (Thursday) 6:00 a.m. to 1:30 p.m.

02/16/17 (Thursday) 6:00 a.m. to 1:00 p.m.

02/17/17 (Friday) 6:00 a.m. to 12:30 p.m.

02/23/17 (Thursday) 6:00 to 1:00 p.m.

c. Staff D, Nurse Practitioner ' s hours were provided by Staff I, Nursing Supervisor on 03/24/17. Interview with Staff I, Nursing Supervisor on 03/24/17 at 9:28 a.m. confirmed Staff D ' s hours were as follows:

Monday through Thursday 5:00 a.m. to 3:00 p.m.

Friday 8:00 a.m. to 3:30 p.m.

d. Staff H, Medical Director ' s hours were provided by Staff I, Nursing Supervisor on 03/24/17. Interview with Staff I, Nursing Supervisor on 03/24/17 at 11:18 a.m. confirmed Staff H ' s hours were as follows:

Monday through Friday 7:00 a.m. to 12:00 noon

e. None of the physician ' s, or registered nurse practitioner ' s hours were on Weekends (Saturday & Sunday) from 6:00 a.m. to 8:00 a.m., or on holidays from 6:00 a.m. to 8:00 a.m. during the program ' s dosing hours on these days.

f. Interview with Staff G, Clinic Director on 03/24/17 beginning at 1:45 p.m. confirmed none of the physician ' s, or registered nurse practitioner ' s hours were on Weekends (Saturday & Sunday) from 6:00 a.m. to 8:00 a.m., or on holidays from 6:00 a.m. to 8:00 a.m. during the program ' s dosing hours on these days.

g. Neither the Registered Nurse Practitioner, the Medical Director, nor the Program Physician work at the opioid treatment program on weekends (Saturday and Sunday) or holidays. Therefore, the opioid treatment program does not have either a physician, physician extender, or registered nurse present during their hours of operation on weekends and holidays from 6:00 a.m. to 8:00 a.m. This was confirmed by interview with the Clinic Director. The program ' s failure to ensure 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 professional: program physician, physician extender, or registered nurse does not meet the intent of the regulation.

Statement of Deficiency

Based on documentation review and interview the program failed to document in the patient ' s record any rejection of prior authorization, rejection of a submitted claim for written denial from a patient ' s insurer or West Virginia Medicaid denying coverage for opioid treatment. Patients affected include but are not limited to three (3) of 18 active patients in the sample. Patient identifiers: Patients #1, #2, and #8. Findings include:

a. Patient #1 was admitted to the program on 02/21/17.

b. Patient #2 was admitted to the program on 02/28/17.

c. Patient #8 was admitted to the program on 02/10/17.

d. Patient #1, #2, and #8 ' s records had no documented evidence of a rejection of prior authorization or rejection of a submitted claim or written denial from an insurer or West Virginia Medicaid denying coverage for opioid treatment.

e. Interview with Staff G, Clinic Director on 03/23/17 at 9:25 a.m. confirmed Patients #1, #2, and #8 ' s records did not contain a rejection of prior authorization or rejection of a submitted claim or written denial from an insurer or West Virginia Medicaid denying coverage for opioid treatment. Later in the same interview Staff G confirmed none of the patients ' records contain this documentation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure a confidential individual personnel file for every clinical staff member or volunteer contained at a minimum, detailed job descriptions. Staff affected: one (1) of six (6) personnel files reviewed. Staff identifier: C. Findings include:

(a) Staff C, Counselor I was hired by the program on 10/17/16. Staff C's personnel file did not have a detailed job description.

(b) Interview on 03/21/17 beginning at 12:05 p.m. on Staff G, Clinic Director confirmed Staff C's personnel file did not have a detailed job description.

(c) The failure of the Program to ensure a confidential individual personnel file for every clinical staff member or volunteer contains at a minimum a detailed job description does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to provide evidence that each opioid treatment program employee, independent contractor, or volunteer has received an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening Unit of the Department of Health and Human Resources. Staff affected: one (1) of six (6) personnel files reviewed. Staff identifier: E. Findings include:

(a) Staff E, Counselor II was hired by the program on 04/11/16. Staff E's personnel file did not have a fingerprint background check or an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening Unit of the Department of Health and Human Resources.

(b) Interview on 03/21/17 beginning at 12:05 p.m. with Staff G, Clinic Director confirmed Staff E's personnel file did not have a fingerprint background check or an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening Unit of the Department of Health and Human Resources.

(c) The failure of the Program to provide evidence that each opioid treatment program employee, independent contractor, or volunteer has received an eligibility fitness determination or variance from the West Virginia Clearance for Access: Registry and Employment Screening Unit of the Department of Health and Human Resources does not meet the intent of the regulation.

Statement of Deficiency

Based on documentation review and interview the program failed to ensure each medication order and dosage change shall be written on an acceptable order sheet and signed and dated by only the program physician. Patients affected: one (1) of eighteen (18) active patients in the sample. Patient identifier: Patient #10. Findings include:

a. Patient #10 was admitted to the program on 01/26/17.

b. Patient #10 ' s record contained a Physician ' s Orders Admission dated 01/26/17 for Methadone, 30 milligrams on 01/26/17. This order was not signed with a legible signature. Section "Patient Name" and Section "Patient# (Patient ' s identification number)" were blank.

c. The six rights of a medication order include but are not limited to the "Right Individual." Patient #10 ' s Physician ' s Orders Admission dated 01/26/17 did not meet the requirements for a proper medication order. The patient was not identified by name or patient identification number any place on this order, which rendered the order null and void.

d. Patient #10 ' s record did not contain any other Physician ' s Orders Admission dated 01/26/17 for the initial dose of medication.

e. Patient #10 ' s "Patient Medication Record" dated from 01/26/17 to 03/22/17 revealed he received the following:

1. Methadone Liquid, 30 milligrams on 01/26/17,
2. Methadone Liquid, 30 milligrams on 01/28/17, and
3. Methadone Liquid, 30 milligrams on 02/22/17.

f. Interview with Staff G, Clinic Director on 03/24/17 beginning at 1:45 p.m.: confirmed Patient #10 received Methadone Liquid, 30 milligrams on 01/26/17 as specified in the Physician ' s Order for Methadone Liquid dated 01/26/17 in his record. Later in the same interview, Staff G confirmed this was the only Physician ' s Orders Admission dated 01/26/17 in Patient #10 ' s record.

g. Patient #10 was admitted on 01/26/17. Patient #10 ' s initial dose of Methadone Liquid, 30 milligrams dispensed on 01/26/17. This was confirmed by interview with the Clinic Director. Although the medication order was written on an acceptable order sheet and signed and dated by only the program physician, it lacked documented evidence of any patient ' s name or identifier, rendering this physician ' s order null and void. Patient #10 ' s record lacked documented evidence of any patient-specific order for the initial dose of Methadone Liquid dated 01/26/17, the date of his admission. The programs failure to ensure each medication order and dosage change shall be written on an acceptable order sheet and signed and dated by only the program physician does not meet the intent of the regulation.

Statement of Deficiency

Based on documentation review and interview the program failed to check the Controlled Substances Monitoring Program database upon admission of the patient, at least every 90 days to determine if controlled substances other than those prescribed medication-assisted treatment medications are being prescribed for the patient, and at each patient ' s physical assessment.

The patient ' s record shall include documentation of the check of the Controlled Substances Monitoring Program database and the date upon which it occurred. Patients affected: one (1) of eighteen (18) active patients in the sample. Patient identifier: Patient #10 and #11. Findings include:

a. Patient #11 was admitted to the program on 10/05/15.

b. Patient #11 ' s record contained three (3) documented checks of the Controlled Substances Monitoring Program database. The first was dated from 06/28/15 to 10/08/15. The second was dated from 07/26/15 to 11/10/15. The third was dated from 11/01/15 to 02/03/16. The dates of these checks did not occur at least every 90 days.

c. Interview with Staff G, Clinic Director on 03/24/17 beginning at 1:45 p.m. confirmed Patient #11 ' s Controlled Substances Monitoring Program database checks did not occur at least every 90 days.

d. Although Patient #11 ' s record contained three (3) documented checks of the Controlled Substances Monitoring Program database dated between 06/28/15 through 02/03/16, these checks did not occur at least every 90 days. This was confirmed by interview with the Clinic Director. The program ' s failure to check the Controlled Substances Monitoring Program database upon admission of the patient, at least every 90 days to determine if controlled substances other than those prescribed medication-assisted treatment medications are being prescribed for the patient, and at each patient ' s physical assessment did not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure individual patient records contain the initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans. Patients affected: two (2) of (18) active patients in the sample. Patient identifiers: #7 and #10. Findings include:

(a) Patient #7 was admitted to the program on 12/14/16. Patient #7's record did not have a completed initial or post-admission individualized treatment plan of care.

(b) Patient #10 was admitted to the program on 01/26/17. Patient #10's record did not have a completed initial or post-admission individualized plan of care. This record contained documents at various stages of completion, signed and dated only by Patient #10 including but not limited to, a blank initial plan of care signed only by the Patient #10 and dated 01/26/17.

(c) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #7 and #10's records did not have an initial or post-admission individualized treatment plan of care.

(d) The failure of the Program to ensure individual patient records contain the initial and post-admission individualized treatment plans of care, and any amendments, reviews or changes to the plans does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the MAT Program failed to ensure every patient undergoes a documented biopsychosocial assessment by a program counselor before admission to the MAT program. The biopsychosocial assessment shall be completed at the time of admission and prior to the first dose of medication-assisted treatment medication. Patients affected: one (1) of 18 active patients in the sample. Patient identifier: #10. Findings include:

(a) Patient #10 was admitted to the program on 01/26/17. Patient #10's record contained no biopsychosocial assessment.

(b) Patient #10's "Patient Medication Record" dated from 01/26/17 to 03/22/17 revealed he received the following: Methadone Liquid, 30 milligrams on 01/26/17; Methadone Liquid, 30 milligrams on 01/28/17; and Methadone Liquid, 30 milligrams on 02/22/17.

(c) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #10 received Methadone Liquid, 30 milligrams on 01/26/17; Methadone Liquid, 30 milligrams on 01/28/17; and Methadone Liquid, 30 milligrams on 02/22/17, prior to undergoing a biopsychosocial assessment by a program counselor.

(d) The failure of the Program to ensure every patient undergoes a documented biopsychosocial assessment by a program counselor before admission to the MAT program and prior to the first dose of medication-assisted treatment medication does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure the initial post-admission assessment shall consist of a medical assessment and include documentation of an inquiry to and report from the Controlled Substances Monitoring Program database. Patients affected: one (1) of 18 active patients in the sample. Patient identifier: #10. Findings include:

(a) Patient #10 was admitted to the program on 01/26/17. Patient #10's record contained no documented evidence of a check of the Controlled Substances Monitoring Program database.

(b) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #10's record contained no documented check of the Controlled Substances Monitoring Program database.

(c) Patient #10's "Patient Medication Record" dated from 01/26/17 to 03/22/17 revealed he received the following medication doses without evidence of a check of the Controlled

Substances Monitoring Program database documented in his record: Methadone Liquid, 30 milligrams on 01/26/17; Methadone Liquid, 30 milligrams on 01/28/17; and Methadone Liquid, 30 milligrams on 02/22/17.

(d) The failure of the Program to ensure the initial post-admission assessment shall consist of a medical assessment and include documentation of an inquiry to and report from the Controlled Substances Monitoring Program database does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure the initial post-admission assessment shall consist of a medical assessment and include documentation of an inquiry to and report from the Controlled Substances Monitoring Program database. Patients affected: one (1) of 18 active patients in the sample. Patient identifier: #10. Findings include:

(a) Patient #10 was admitted to the program on 01/26/17. Patient #10's record contained no documented evidence of a check of the Controlled Substances Monitoring Program database.

(b) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #10's record contained no documented check of the Controlled Substances Monitoring Program database.

(c) Patient #10's "Patient Medication Record" dated from 01/26/17 to 03/22/17 revealed he received the following medication doses without evidence of a check of the Controlled Substances Monitoring Program database documented in his record: Methadone Liquid, 30 milligrams on 01/26/17; Methadone Liquid, 30 milligrams on 01/28/17; and Methadone Liquid, 30 milligrams on 02/22/17.

(d) The failure of the Program to ensure the initial post-admission assessment shall consist of a medical assessment and include documentation of an inquiry to and report from the Controlled Substances Monitoring Program database does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure after a program physician or supervised physician extender performed a physical assessment of the patient on the same day that the program physician initially prescribed, dispensed or administered a medication-assisted treatment, and the patient continued to be treated for substances use disorder at the program, an assessment was performed at least every 90 days thereafter. Patients affected: two (2) of 18 active patients in the sample. Patient identifiers: #3 and #15. Findings include:

(a) Patient #3 was admitted to the program on 10/03/13. Patient #3's record did not contain an assessment at least every 90 days after 10/17/16.

(b) Patient #15 was admitted to the program on 02/27/14. Patient #15's record did not contain an assessment at least every 90 days in 2016.

(c) Interview on 03/21/17 at 2:30 p.m. with Staff G, Clinic Director confirmed Patient #3's record did not contain an assessment at least every 90 days after 10/17/16. In the same interview, Staff G confirmed Patient #15's record did not contain an assessment at least every 90 days in 2016 until present. Staff G confirmed the program completed physical assessments annually.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure within 30 days after admission of a patient, the MAT program developed a more comprehensive individualized treatment plan of care and attached 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 Dependence (AATOD), or such other nationally recognized authority approved by the secretary. The individualized treatment plan of care shall include a recovery model based upon the approved guidelines and protocols. Patients affected: one (1) of (18) active patients in the sample. Patient identifier: #7. Findings include:

(a) Patient #7 was admitted to the program on 12/14/16. Patient #7's record did not have a more comprehensive individualized treatment plan of care developed within 30 days after admission.

(b) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #7's record did not have a more comprehensive individualized treatment plan of care developed within 30 days after admission.

(c) The failure of the Program to ensure within 30 days after admission of a patient, the MAT program developed a more comprehensive individualized treatment plan of care and attached it to the patient's chart no later than five days after the plan is developed does not meet the intent of the regulation.

Statement of Deficiency

(1) Based on documentation review and interview, the Program failed to ensure the individualized treatment plan of care was 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 shall be documented in the patient's record. Paper and electronic plans of care, including all reviews and updates, must be acknowledged by the patient. Patients affected: one (1) of (18) active patients in the sample. Patient identifier: #12. Findings include:

(a) Patient #12 was admitted to the program on 07/02/13. Patient #12's record had no individualized treatment plan of care review since 08/05/16. The 90-day reviews should have occurred twice since this date.

(b) Interview on 03/24/17 beginning at 1:45 p.m. with Staff G, Clinic Director confirmed Patient #12's record had no individualized treatment plan of care review since 08/05/16. Later in the same in interview, Staff G confirmed the 90-day reviews should have occurred twice since this date.

(c) The failure of the Program to ensure the individualized treatment plan of care was reviewed by the program physician, primary counselor and patient at least every 90 days and documented in the patient record does not meet the intent of the regulation.