

RETURN RECEIPT

E-MAIL TRANSMISSION TO: luke.mohr@ctcprograms.com

October 1, 2021

Luke Mohr, Program Sponsor
CRC Recovery Inc. DBA Cedar Rapids Treatment Center
5005 Bowling Street, SW Ste. C
Cedar Rapids, Iowa 50404

RE: Complaint Investigation BH-1224-052521

Dear Mr. Mohr:

Enclosed please find a copy of the Complaint Investigation Report that was the result of investigation by the Division. This report and its findings will be presented during the Iowa Board of Health Substance Abuse/Program Gambling Program Licensure Committee meeting on Wednesday, **October 13, 2021 at 9:00 a.m.** The meeting will be held via teleconference. Please let me know if you would like to participate in this meeting and a phone number will be provided to you. ***Program representation is welcomed but not required.***

Should you have any questions, please feel free to contact me at Lori.Hancock-Muck@idph.iowa.gov or at (515) 204-9766.

Sincerely,



Lori Hancock-Muck
Health Facilities Officer
Division of Behavioral Health

cc: Heather Adams, Assistant Attorney General
Substance Abuse/Problem Gambling Program Licensure Committee

IOWA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF BEHAVIORAL HEALTH

COMPLAINT INVESTIGATION REPORT

PROGRAM: CRC Recovery Inc., dba Cedar Rapids Treatment Center (CRC)
5005 Bowling Street, SW, Suite C
Cedar Rapids, Iowa 52404

LICENSED SERVICES: Adult Opioid Treatment Program Services

PREVIOUS COMPLAINTS: BH-1181-012417 (previous report attached)

INVESTIGATORS: Lori Hancock-Muck, Division of Behavioral Health
Kevin Gabbert, Division of Behavioral Health

COMPLAINT #: **BH-1224-052521**

DATE OF COMPLAINT: May 25, 2021

INVESTIGATION TIMELINE: May 25, 2021 to September 15, 2021

DATE OF REPORT: September 15, 2021

SUMMARY OF FINDINGS:

1. Safe containing methadone is left unlocked and open at all times as no staff have the code for the safe. (SUBSTANTIATED)
2. The alarm for the medication room (where the safe is housed) has not been activated, as the safe has to be locked in order for this to be possible. (SUBSTANTIATED)
3. A staff member left her window open overnight during the time the safe was not locked and the alarm was not activated. (SUBSTANTIATED)
4. Counseling staff have provided dosing of methadone to patients. (SUBSTANTIATED)
5. Unauthorized individuals have repeatedly been in the restricted medication area, including a young child and a formerly employed nurse. (SUBSTANTIATED)
6. Missing or unaccounted for medication (Suboxone). (SUBSTANTIATED)
7. Pill bottles and methadone bottles are left out on counters unsecured. (SUBSTANTIATED)
8. There are no nursing staff employed at the facility. (SUBSTANTIATED)
9. Medication bottles are not labeled. (SUBSTANTIATED)
10. Incident reports are not maintained in personnel or patient records. (SUBSTANTIATED)
11. Appropriate protocols are not being followed for properly disposing of unused medications. (SUBSTANTIATED)

NATURE OF COMPLAINT:

On May 25, 2021, the Iowa Department of Public Health (Department) received an anonymous complaint reporting the follow allegations against CRC:

- *Safe containing methadone is left unlocked and open at all times as no staff have the code for the safe.*

It was reported that a former employee had to be contacted by CRC to come into the facility to unlock the safe where narcotic medications were stored, as no one at the facility knew the safe code combination. It was further reported that this same former employee helped dose patients that day.

- *The alarm for the medication room (where the safe is housed) has not been activated, as the safe has to be locked in order for this to be possible*

It was reported that the security alarm to the medication room was intentionally not activated, as no one at CRC knew the code to the safe.

- *A staff member left her window open overnight during the time the safe was not locked and the alarm was not activated.*

It was reported that staff arrived one morning to find the clinical supervisor's office window was left open overnight. This occurred during a night where narcotics were left in an unlocked safe in the medication room, which did not have an alarm activated.

- *Counseling staff have provided dosing of methadone to patients.*

It was reported that counselors were asked by the clinical director to assist with dispensing methadone to patients, as there was an abrupt shortage of nursing staff.

- *Unauthorized individuals have repeatedly been in the restricted medication area, including a young child and a previously employed nurse.*

It was reported that the clinical director brought her two young children to the facility and allowed them to be in the medication room, which is restricted to nursing staff only. It was also reported that a formerly employed nurse had to be contacted to come to the facility to unlock the safe, as she was the only one who knew the code. It was reported that this formerly employed nurse remained at the facility to dose patients after unlocking the safe.

- *Missing or unaccounted for medication (Suboxone).*

It was reported that there has been no reconciliation for missing medications at the facility.

- *Pill bottles and methadone bottles are left out on counters unsecured.*

It was reported that narcotics, to include Suboxone and methadone, are unsecured and there were pills laying on the countertops of the medication room.

- *There are no nursing staff employed at the facility.*

It was reported that the facility's nursing staff had either quit, been terminated, or had not reported to work. It was reported that operations have continued at the facility with dosing being conducted by unqualified staff.

- *Medication bottles are not labeled.*

It was reported that an inmate patient was dispensed methadone and not all medication bottles had labels with the patient's name and dose. As a result, the jail was unable to dispense the medication to the patient.

INVESTIGATION AND FINDINGS:

Following receipt of the complaint, investigators contacted the Linn County jail on May 27, 2021 to interview medical staff about the inmate who allegedly was provided unlabeled medication bottles from CRC. The investigator spoke with the medical unit nurse who reported one inmate had missed at least one day of methadone due to CRC not labeling the bottles and not providing a chain of custody form. The nurse reported she was told by CRC that a federal exception request was provided for the inmate through the weekend however when they transported the inmate to CRC, they learned the request was not approved. The nurse left voice messages at CRC and no one returned a call until four days later. The nurse spoke to the clinical supervisor who reported to her they had the exception approved, and the inmate was then transported back to CRC and was dosed but returned with six unlabeled bottles and, again, no chain of custody. The nurse called CRC again and no one returned her call until the following day when the counselor told her "someone or the doctor" would call her back. The nurse reported that was two days ago and today she received a call from CRC informing her another exception request was approved for 7 days. The nurse reported the plan was to transport the inmate back to CRC to return the six unlabeled bottles to be replaced with six labeled bottles and chain of custody. The nurse stated she has instructed the transporting officer to make sure to check for labels and the chain of custody form. The nurse reported this is the first time this type of incident has occurred but "since the director changed in the last month, CRC has not been responsive and does not return calls." The nurse reported it is "difficult to coordinate services with them", and the jail may need to determine a plan to taper inmates if the jail continues to have problems with CRC.

Due to the safety and welfare issues associated with the reported allegations along with the Linn County jail staff's confirmation of CRC dispensing medications without labels, it was determined that investigators would conduct an immediate unannounced inspection at CRC. Prior to the inspection, investigators notified agents from the Drug Enforcement Agency about the allegations and the Department's decision to conduct the unannounced inspection. In addition, a referral to the Iowa Department of Inspections and Appeals was made on June 4, 2021 due to possible fraudulent billing practices as it was alleged that counselors were dosing patients on May 25 and May 26, 2021.

On May 28, 2021, investigators conducted the unannounced inspection at CRC. The investigators met with Audrey Wilson (CRC's Clinical Supervisor) as she informed investigators that she was the person overseeing operations that day. Ms. Wilson fully cooperated with the unannounced inspection and complied with the investigators request for a walk-through of the facility. While being escorted to the medication room, investigators saw numerous patients standing in the lobby appearing frustrated with the dosing process and one yelled out "it's been like this all week." The investigators were then escorted to the medication room where two nurses were dosing patients from two different windows. Investigators were told the two nurses were brought in from another Opioid Treatment Program from the state of Virginia, as there were no employed nurses at CRC to dose patients. The two nurses were employed by Acadia, which is CRC's corporate company. The nurses openly shared with investigators that they arrived two days prior and were "shocked" at what they saw when they arrived at CRC. They reported when they first arrived, "(medication) bottles were everywhere" and "pill bottles without lids just sitting out". The

nurses also reported pills were “just sitting out here on the counter” and that there were unreconciled medications. Ms. Wilson acknowledged to the investigators that there were no nurses on staff earlier in the week as they either had quit or never reported to work. Ms. Wilson told investigators that a formerly employed nurse had to be contacted for her to come to the facility to unlock the safe containing the medications, as no one knew the code. Ms. Wilson said the former staff person arrived at the facility, unlocked the safe, and then helped dose patients. Ms. Wilson said the safe had been left unlocked for at least two days, as no one knew the safe code. Ms. Wilson told investigators during those two days, CRC’s medical physician, clinical director, a previously employed nurse and a counselor all dosed patients. Ms. Wilson acknowledged to investigators that she also helped dose patients during that period and that CRC’s Clinical Director, Sheila Roggentien, talked her through the process of dosing. Ms. Wilson told investigators that Ms. Roggentien has not reported to work since May 26, 2021, and “no one knows where she is at.” Ms. Wilson also stated that CRC’s Regional Director, Sheila Paden, made the decision on May 26, 2021 (two days following the nurse shortage) to have compact nurses from Acadia come to the facility to assist with dosing.

Following the inspection of the medication room, the investigators viewed recorded footage from the medication room cameras during the inspection, which was located in a counselor’s office. The counselor in that office was able to assist the investigators with identifying the staff in the video footage. The investigator viewed video footage of Ms. Roggentien, the medical physician, and counselors dosing patients from the medication room on May 25, 2021 and on May 26, 2021. Investigators saw a counselor, who also appeared to be alone in the medication room dosing patients. The counselor assisting the investigators with the video footage identified the counselor in the video as a counselor who was currently on site working during the inspection.

The investigators interviewed the counselor, who was observed on the video dosing patients by herself. The counselor reported on May 25, 2021, she came to work to find there were no nurses on site and only the clinical director (Randi Roggentien, Licensed Practical Nurse) was there. The counselor reported Ms. Roggentien asked her “What do we do?” The counselor stated there were already several patients who had been waiting 30 minutes to be dosed. The counselor said she told Ms. Roggentien that she would have to dose the patients, as she was the only one with the credentials to do so. She stated Ms. Roggentien instructed the counselor to follow her into the medication room even though both knew she was not authorized to be in the medication room. She stated Ms. Roggentien told her that she did not know how to do the dosing and would need the counselor to show her how to do it. The counselor told investigators she logged into the system using Ms. Roggentien’s login information and then showed her the process of dosing. The investigators asked the counselor how she knew how to do the dosing if she had never been in the medication room before to which she responded, “I mean it’s common sense really...you know, like the methadone sits here and there’s a tube coming out so you put the cup there.” The counselor continued to explain to investigators the dosing process. She stated Ms. Roggentien had never dosed the patients before so the counselor had to explain the process to her. The counselor acknowledged dosing a couple of patients but spent most of the time “keeping Randi calm.” The counselor stated that at one point Ms. Roggentien said, she had to go to

the restroom and the counselor responded, “I’m not supposed to even be in here so if you’re going to go to the bathroom then we need to stop medicating.” The counselor told investigators Ms. Roggentien then told her she was “going to have a panic attack and started to break down in front of me and started crying”. The counselor said Ms. Roggentien then left the room and the counselor stated the patients continued to present at the window so she made the decision to continue dosing the patients after Ms. Roggentien left the room. The counselor said after two or three patients were dosed, she stopped dosing and went to the receptionist desk as Ms. Roggentien had been gone for approximately 20 minutes. She said she asked reception staff where Ms. Roggentien was and they told her she got in her car to drive off, but her tires became stuck in the mud. She said it was at that point staff were able to persuade Ms. Roggentien to come back into the facility to continue assisting with dosing. The counselor reported that at this point some of the patients had been waiting up to two hours to be dosed. The counselor reported she then went back to her office and “just sat there as I knew I had done something wrong.” The counselor told investigators she was fearful there would have been negative consequences if she had not helped dose patients that day. It should be noted that following the inspection, the interviewed counselor and Ms. Wilson were immediately placed on administrative leave and soon after their employment was terminated.

At the conclusion of the inspection, the investigators participated in a call with Ms. Paden and Luke Mohr (CRC’s Program Sponsor and Regional Vice President) to review the preliminary findings of the unannounced visit. Investigators shared the immediate health, safety, and welfare issues with Ms. Paden and Mr. Mohr. Ms. Paden stated she was not aware of the staffing issues at the facility and would be returning to CRC immediately as she was currently out of state. Following the unannounced inspection, the Department determined to issue an emergency monitor order based on the health, safety, and welfare issues that were found from the inspection.

Emergency Monitor Order – June 3, 2021

Due to the investigators’ findings from the unannounced inspection at CRC on May 28, 2021, it was determined that continued operation of CRC without a monitor constituted an immediate threat to the health, safety, and welfare of patients. As a result, on June 3, 2021 the Department placed Misty Angrick to serve as a monitor at CRC pursuant to Iowa Code section 125.15A Licensure Emergencies. Ms. Angrick was assigned to serve at CRC to observe operations of CRC, assist CRC with advice regarding compliance with state regulations, and report on a weekly or as needed basis to the Department regarding operations of the program. Ms. Angrick performed on site monitoring activities for eight days, which consisted of observation of dosing procedures, interviewing staff, and reviewing current policies and protocols. Ms. Angrick found the following concerns through observation or through staff/patient interviews during her monitoring activities:

- Dosing hours were not conducive for the volume of patients being dosed, as there were wait times of over an hour at times and the waiting room was overly crowded. Elderly patients were complaining about standing too long.
- Clinical supervisor’s office window had been left open on May 25 and May 26. These windows are crank operated windows with screens but could be accessed if attempted.

- Two counselors, an ex-employee, clinical supervisor, and the medical physician dosed patients on May 25 and May 26, 2021. These staff were neither qualified nor formally trained to dose patients.
- During staff interviews, four staff members told the monitor the clinical director's young child was allowed in the medication room for 15 minutes with methadone in his hand for a "quick second".
- Medical physician had thrown pills in the trash after they had fallen on the floor.
- Multiple patients returned to the clinic with unlabeled bottles.
- Appropriate protocols were not being followed for properly disposing of unused medications.
- Regional Director (Ms. Paden) was aware of the nurse staffing issue and reportedly told staff "do whatever it takes to get the patients dosed." It was further reported that Ms. Paden was aware on May 25 there were no nurses available to dose, however waited until May 27 to send replacement nurses from Acadia. Ms. Paden denied knowledge of this during an interview with the monitor and stated she had contacted Luke Mohr once she determined no nurses were available to dose. It was further reported by interviewed staff that Ms. Paden is very difficult to work with. The monitor asked interviewed staff what would need to happen to improve patient care and retention and almost all staff stated Ms. Paden was the issue and, "should be let go, and replaced by someone who has experience and cares about the patient and not the money." It was reported seven employees, including four nurses, have quit within the six months since Ms. Paden was hired. The monitor noted many staff reported being fearful of filing complaints due to possible retaliation.
- Cameras are not positioned over the dosing areas, which does not allow a visual of doses going out, or patients taking medications to prevent diversion.
- Patients are not given a full amount of take homes as medications were on backorder.
- Medical physician admitted to one pill falling in trash when dosing a patient and replacing it with another. She reported not knowing this required an incident report.
- Take home bottles are not labeled as it was reported Ms. Roggentien told the medical physician that labels were not needed if bottles were going in a locked box.
- Team meetings have been phased out by Ms. Paden, which makes it difficult for staff to discuss important safety information and patient care issues with the medical physician.
- During an interview with a patient, the monitor was told, "Never in his nine months of coming to the clinic has he had to wait for his buprenorphine to melt at the window."
- Facility is unkempt, as the janitorial service had quit. Ms. Paden reported not being aware of this until she had arrived at the office and saw the termination letter on her desk.
- During the second and third day of monitoring, the monitor reviewed the medication inventory count at the end of the shift, and there were overages.
- Monitor witnessed two medication errors as two patients were given double doses as the nurse accidentally hit the spacebar on the computer, which triggered the double dosing. The monitor reported there was a lack of follow up provided for these two patients to monitor for side effects. Patients were told they would receive a follow up phone call later in the afternoon for a wellness check. The facility had no Narcan

- kits on site for the emergency treatment of known or suspected opioid overdose. It was reported to the monitor that it is against policy to have these kits at their facility.
- Trash dumpster at the facility was not locked and left unsecured as other tenants in the building use the same dumpster. CRC has since ordered a new locked dumpster, which only CRC will be able to access.

Weekly calls with CRC Executive Leadership Staff

Beginning June 3, 2021, Department staff held weekly virtual calls with Luke Mohr (CRC's Program Sponsor and Regional Vice President) and Ruth Moore (Acadia Healthcare Sr. Vice President, Compliance/Chief Privacy Officer). During these weekly calls, Mr. Mohr and Ms. Moore provided weekly updates of progress being made at CRC. Each week, Mr. Mohr and Ms. Moore reported out specific activities for improvement and appropriately addressed immediate safety and welfare issues at the facility. Each week, the Department found CRC was making notable progress to include hiring qualified nurses and clinical staff. Mr. Mohr and Ms. Moore fully cooperated with the investigation and were extremely responsive to all recommendations and requests made by the Department. Significant progress was noted in wait times as wait times for dosing dropped from over an hour wait to averaging less than 4 minutes wait time. Hiring was also prioritized by leadership staff and within weeks, the location was fully staffed with qualified nurses. In addition, the previous clinical director, Jackie Scott, was rehired as the Clinical Director. The Department investigators found Ms. Scott to be well qualified for the position. Ms. Scott resumed her position as clinical director on August 23, 2021. Other areas of improvement found from weekly calls included the following:

- The monitor reported positioning of cameras should be directly over the dosing area, as the current cameras did not have this view. As a result, the Department recommended CRC install a camera directly in view of the dosing window. Mr. Mohr arranged with the security camera vendor to add cameras to the dosing room so that the dosing window and alarm panel would be recorded. There have been continued vendor delays in the work order being completed but Mr. Mohr has assured Department investigators this will be completed.
- Narcan kits were ordered for the facility, and staff were trained on proper administration of Narcan.
- Based on a needs assessment, corporate staff from Acadia came on site to provide staff development training on topics to include but not limited to corporate compliance, proper use of Methasoft methadone software program, critical incident reporting, process for medication reconciliation, and confidentiality/privacy laws and regulations.
- Acadia's Corporate Medical Director has had weekly contact with the facility's medical physician to offer additional support and guidance.
- Weekly staff meetings have resumed with the facility's medical physician and counseling staff.
- A supervising nurse from Acadia remained at the facility to oversee dosing procedures until Ms. Scott was hired. Following Ms. Scott's hiring, the Department agreed to amend the emergency order on August 26, 2021, to remove an Acadia nurse from being physically present at the facility with the condition that the facility be appropriately staffed to oversee medical, clinical and program operations. In

addition, CRC was required to allow the facility nurses with video and audio access to a supervising nurse from Acadia until a permanent on site supervising nurse was employed at the facility.

- Revision of take-home protocols to ensure efficient and timely process.

Due to CRC demonstrating continued progress during the course of the monitoring order, the Department made three different amendments to the emergency monitoring order as follows:

Amended Emergency Monitor Order – June 8, 2021

On June 3, 2021, CRC submitted a request to the Department to amend the Order to remove the requirement that the two current out-of-state compact nurses from Acadia be replaced with other qualified nurses as the current compact nurses were slated to return to their home states. The Department amended the order on June 8, 2021 to allow two alternative out-of-state compact nurses from Acadia to remain at CRC to provide the methadone dosing until qualified nursing staff could be hired and fully trained.

Amended Emergency Monitor Order – June 28, 2021

The Department determined CRC took immediate action to rectify the emergency and had shown full compliance with the Emergency Order to include compliance with the recommendations made by the Department and by the monitor. As a result, the emergency order was amended again to withdraw the monitor from serving at the facility to observe program operations. Additionally, as the facility was fully staffed with appropriately credentialed nurses, the Department determined it was not necessary for two out-of-state compact Acadia nurses to be on site as long as a supervising nurse from Acadia remained on site to continue training and onboarding of the newly hired staff. The Order required continued attendance of weekly calls by CRC and the Department until a full investigation could be completed.

Amended Emergency Monitor Order – August 26, 2021

Following the hiring and start date of Jackie Scott as the new Clinical Director, the Department determined CRC had hired appropriately credentialed and qualified staff to continue operations of the program. As a result, the order was amended to no longer require a supervising nurse from Acadia to remain on site on the condition that the facility continued to be appropriately staffed to oversee medical, clinical, and program operations. In addition, CRC was to continue to allow the facility nursing staff with video and audio access to a supervising nurse from Acadia until a permanent on site supervising nurse became employed at the facility.

CONCLUSIONS:

Allegation #1:

SUBSTANTIATED

Safe containing methadone is left unlocked and open at all times as no staff have the code for the safe.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)“d”.

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

The allegation that the safe containing methadone is left unlocked and open at all times as no staff have the code for the safe was found to be substantiated. All interviewed staff acknowledged to investigators that the safe containing narcotics had been left unlocked for two days as no one knew the safe code, and staff would not have been able to dose patients if the safe were locked. With the monitoring activities, the safe codes were changed, and appropriate nursing staff were provided with the codes. The monitor also observed the safe being locked unless in use. With onsite monitoring activities in place, the monitor observed proper protocols were being followed with securing the safe and medication room.

Allegation #2

SUBSTANTIATED

The alarm for the medication room (where the safe is housed) has not been activated, as the safe has to be locked in order for this to be possible.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

(1) There shall be specific methods for control and accountability of medication products throughout the program.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

The allegation the alarm for the medication room (where the safe is housed) has not been activated, as the safe has to be locked in order for this to be possible was found to be substantiated. Through staff interviews, there was corroborated information to support the finding that the safe had been left unlocked, as none of the staff knew the safe code. As a result, staff reported the alarm was not activated. With onsite monitoring activities in place, the monitor observed the safe codes were changed, and appropriate nursing staff maintained these codes. The monitor also observed proper protocols were being followed for activation of alarms.

Allegation #3

SUBSTANTIATED

A staff member left her window open overnight during the time the safe was not locked and the alarm was not activated.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

The allegation a staff member left her window open overnight during the time the safe was not locked and the alarm was not activated was found to be substantiated. Interviewed staff reported to the monitor that the clinical supervisor had left her window open overnight on

May 25 and May 26, 2021. On these two dates, the safe containing narcotics was left unlocked, and the alarm to the medication room was not set. Although the monitor found the windows to be crank operated windows with screens, it was reported by the monitor that entry through the window could have been accessed if attempted.

Allegation #4

SUBSTANTIATED

Counseling staff have provided dosing of methadone to patients.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1) "d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(3) Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

a. Staff authorized to administer medications shall be qualified, and a current list of such staff shall be maintained. The following health professionals are designated by rule 657—8.32(124,155A) as qualified individuals to whom a prescriber can delegate the administration of medications:

(1) Persons who have successfully completed a medication administration course reviewed by the board of pharmacy.

(2) Advanced emergency medical technicians and paramedics.

(3) Licensed physician assistants.

(4) Licensed pharmacists.

(5) Nurses, interns or other qualified individuals delegated the responsibility to administer medications by a prescriber licensed by the appropriate state board to administer medications to patients, in accordance with Iowa Code section 155A.4(2) "c."

c. Self-administration of medication shall be observed by a staff person who has been oriented to the program's policies and procedures on self-administration. Self-administration of medication shall be permitted only when the patient's medication is clearly labeled. The policies and procedures on self-administration shall include:

(1) Medications are ordered or prescribed by a prescriber.

(2) The prescriber agrees that the patient can self-administer the medication.

(3) The medication taken and how and when the medication is taken are documented in the patient record.

641 IAC 155.35(8) Medication administration.

b. The initial dose of medication shall not exceed 30 milligrams, and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's case record that 40 milligrams did not suppress opiate abstinence symptoms. A patient transferring into the program or on a guest-dosing status may receive an initial dosage of no more than the last daily dosage authorized by the former or primary program.

(1) Medication shall be administered by a professional authorized by law.

The allegation that counseling staff have provided dosing of methadone to patients was found to be substantiated. The investigators found evidence of this through observing previously recorded video footage where non-qualified staff were in the medication room dosing patients. Investigators also interviewed a counselor and clinical supervisor who both acknowledged they had provided dosing to patients during the two days when there was a nursing shortage at the facility. Due to the potential for fraudulent billing, on June 4, 2021, the Department made a referral to Jeremy Ingram, Bureau Chief at Medicaid Fraud Control Unit with the Iowa Department of Inspections & Appeals.

Allegation #5:

SUBSTANTIATED

Unauthorized individuals have repeatedly been in the restricted medication area, including a young child and a formerly employed nurse.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(3) Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(10) Patient records. The program's policies and procedures shall describe compilation, storage and dissemination of patient records and release or disclosure of information.

f. The program shall release or disclose information on individuals seeking program services or on patients in strict accordance with the Health Insurance Portability and Accountability Act (HIPAA) and state and federal confidentiality laws, rules and regulations.

(1) The confidentiality of substance use disorder patient records and information is protected by HIPAA and the regulations on confidentiality of alcohol and drug abuse

patient records, 42 CFR Part 2, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse patient records.

The allegation that unauthorized individuals have repeatedly been in the restricted medication area, including a young child and a formerly employed nurse was found to be substantiated. Several staff reported to the monitor that the Clinical Director brought her young child to the facility and was allowed in the restricted medication room for approximately 15 minutes, and during that time, the child had methadone in his hand for a “quick second.” Staff also reported to the monitor and investigators that a previously employed nurse was contacted by CRC to come to the facility to unlock the safe containing narcotics as no one knew the code to unlock the safe. It was reported by staff that once the former employee came to the facility to unlock the safe, she stayed and helped dose patients. Investigators also found evidence of this through video footage.

Allegation #6:

SUBSTANTIATED

Missing or unaccounted for medication (Suboxone).

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)“d”.

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(3) Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program’s policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

The allegation that missing or unaccounted for medication (Suboxone) was found to be

substantiated. CRC staff admitted to investigators and to the monitor that medications were not reconciled, and at least one pill was thrown in the trash after it was dropped on the floor by the medical physician. It was also reported to investigators that the compact out-of-state nurses arrived at the facility to find numerous pills laying out on the countertop of the medication room. The monitor reported to investigators that during the first three days of monitoring, she reviewed the inventory count at the end of the shift, and there were overages. The monitor also observed a medication error when a nurse accidentally provided two doses of buprenorphine to two different patients. The monitor reported to the investigators that the facility was instructed by the Drug Enforcement Agency “to do a complete inventory and reconciliation and to start fresh.”

Allegation #7:

SUBSTANTIATED

Pill bottles and methadone bottles are left out on counters unsecured.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)“d”.

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(3) Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program’s policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

The allegation that pill bottles and methadone bottles are left out on counters unsecured was found to be substantiated. Investigators were told by the compact out-of-state nurses that when they arrived at the facility they saw opened pill bottles and pills laying out on the countertops of the medication room.

Allegation #8:

SUBSTANTIATED

There are no nursing staff employed at the facility.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

(3) Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.

(9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

a. Staff authorized to administer medications shall be qualified, and a current list of such staff shall be maintained. The following health professionals are designated by rule 657—8.32(124,155A) as qualified individuals to whom a prescriber can delegate the administration of medications:

(1) Persons who have successfully completed a medication administration course reviewed by the board of pharmacy.

(2) Advanced emergency medical technicians and paramedics.

(3) Licensed physician assistants.

(4) Licensed pharmacists.

(5) Nurses, interns or other qualified individuals delegated the responsibility to administer medications by a prescriber licensed by the appropriate state board to administer medications to patients, in accordance with Iowa Code section 155A.4(2)"c."

641 IAC 155.35(8) Medication administration.

b. The initial dose of medication shall not exceed 30 milligrams, and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's case record that 40 milligrams did not suppress opiate abstinence symptoms. A patient transferring into the program or on a guest-dosing status may receive an initial dosage of no more than the last daily dosage authorized by the former or primary program.

(1) Medication shall be administered by a professional authorized by law.

The allegation that no nursing staff are employed at the facility was found to be substantiated. During the unannounced visit, the clinical supervisor confirmed that no nursing staff were currently employed at the facility as former nurses either had resigned or had not reported to work. At the time of the unannounced visit, the investigators observed

two compact out-of-state nurses dosing patients who reported to investigators that they were temporarily assigned to the facility, as there were no current nurses employed at the facility.

Allegation #9

SUBSTANTIATED

Medication bottles are not labeled.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

d. Prescription medication shall not be administered to or self-administered by a patient without a written order signed by a prescriber. All prescribed medications shall be clearly labeled indicating the patient's full name, the prescriber's name, the prescription number, and the name and strength of the medication, the dosage, the directions for use, and the date of issue; and the name, address and telephone number of the pharmacy or prescriber issuing the medication. Medications shall be packaged and labeled according to state and federal guidelines.

The allegation that medication bottles are not labeled was found to be substantiated. Through an interview with Linn County jail, it was determined that an inmate's medication bottles were provided by CRC without any labels. This was also confirmed by CRC staff who informed investigators that labels were not printed due to the label maker being empty. It was also reported to investigators and the monitor that several patient medication bottles were unlabeled and multiple patients returned to CRC with unlabeled medication bottles.

ADDITIONAL FINDINGS AS A RESULT OF THE INVESTIGATION:

Substantiated Finding #10

SUBSTANTIATED

Incident reports are not maintained in personnel or patient records.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

641 IAC 155.21(8) Personnel. The program shall have personnel policies and procedures.

d. The program shall maintain a personnel record on each staff person. The record shall contain, as applicable:

(3) Incident reports.

641 IAC 155.21(14) Patient record contents. The program's policies and procedures shall require that a record be maintained for each patient and shall specify the contents of the patient record.

a. The patient record shall include:

(11) Any incident report.

As a result of the investigation, it was determined that incident reports were not being documented in patient or personnel records. Through monitoring activities, it was determined that staff were not documenting incident reports for medication errors, and staff reported not being trained on the process for incident reporting. The monitor reported staff were not documenting incident reports following medication errors. Although it was determined that some incidents were being documented through an internal system, incident reports for personnel and patients were not being maintained in personnel records nor in patient records.

Substantiated Finding #11

SUBSTANTIATED

Appropriate protocols are not being followed for properly disposing of unused medications.

641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".

155.10(1)d. Violation of any of the following grounds for discipline:

(2) Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.

641 IAC 155.21(18) Medication control. The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

f. Accountability and control of medications.

(5) Unused prescription medication prescribed for a patient who leaves a program without the patient's medication shall be destroyed by a staff person with a staff witness, and a notation shall be made in the patient record. When a patient is discharged or leaves the program, medication currently being administered shall be sent, in the original container, with the patient or with a responsible agent, as approved by a prescriber.

As a result of the investigation, it was determined that appropriate protocols were not being followed for properly disposing of unused medication. During the onsite inspection, the investigators were told by the clinical supervisor that patients dispose of their unused medications by one nurse observing the patient flushing the unused medication in the bathroom. The monitor recommended use of safe medication disposal by purchasing a drug deactivation system (i.e., Deterra, MedSafe).

PROGRAM RESPONSE:

Program response attached.

RECOMMENDATIONS:

Based on the substantiated allegations above, the Division recommends that the Iowa Board of Health Substance Abuse/Problem Gambling Program Licensure Committee requires CRC to submit to the Division, within 20 business days following receipt of this report, a written plan of corrective action in accordance with Iowa Administrative Code 641 – 155.16(4)(c) that includes the following:

1. Conduct a needs assessment to determine CRC’s organizational and clinical needs. The needs assessment shall include patient and staff input to identify and develop outcome goals. The needs assessment shall also include the recommendations made by the monitor during the emergency monitor order.
2. Establish, ensure, arrange, and monitor quality improvement activities that focus on program services and operations to include, but not limited to, the substantiated allegations found as a result of the investigation. The plan shall include documentation of the frequency of those activities.
3. Create a contingency plan to determine a course of action for CRC to respond effectively to any future unexpected events or situations. The contingency plan should contain potential threats to critical resources including but not limited to staff shortage, equipment (i.e., label makers), medication supply shortages, etc. It is recommended to use a SWOT analysis to analyze the overall operations of the facility.
4. Ensure proper cameras are installed to provide direct viewing over the dosing areas.
5. Review incident-reporting policies to determine if any updates are needed. Provide training to all CRC staff on incident reporting requirements.

The Department has determined CRC has taken immediate corrective actions to eliminate the immediate health, safety, and welfare issues and recommends the Committee approve the Department’s withdrawal of the emergency order once the Department has received and approved the program’s written corrective action plan.



Cedar Rapids

Comprehensive Treatment Center
Opioid Use Disorder Program

Since 2014, Cedar Rapids Comprehensive Treatment Center (CTC) has provided medication-assisted treatment and counseling services in an outpatient setting to help individuals struggling with opioid addiction in the Cedar Rapids community. Throughout that time, we have been fully accredited by CARF and licensed by the IDPH. Our valued clinical staff has successfully treated thousands of patients and they remain committed to providing quality care to our patients.

At Cedar Rapids CTC we hold ourselves to high clinical and quality standards, because our primary concern is the health and safety of our patients and staff. We are committed to maintaining the confidence of our community and to improving the lives of our patients, which is why we have been, and will continue to, work closely with our oversight agencies, including the Iowa Department of Public Health, to address all of their concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'Luke Mohr', with a horizontal line underneath.

Luke Mohr- Program Sponsor