COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

September 11, 2024

Andrew Johnson

RE: Buena Vista Correctional Complex
Complaint #: CO00036221

Dear Mr. Johnson:

The Colorado Department of Public Health and Environment has concluded an investigation of your allegation(s) under the authority of the Colorado Department of Public Health & Environment utilizing the regulations governing Community Clinics and Community Clinics and Emergency Centers.

A regulatory review was completed on 8/29/24. Sixteen patients were included in the sample for this review. Facility documents were reviewed. Eleven staff members were interviewed. Observations were conducted throughout the facility.

The allegation the facility failed to provide pharmaceutical services within recognized standards and facility policy by ensuring patients were monitored after receiving medications was substantiated.

The facility failed to comply with state regulations pertaining to the subject of the allegation.

Based on observations, interviews, and document review, the facility failed to ensure nursing staff monitored patients receiving medications to prevent diversion and unauthorized access.

The facility was cited with deficient practice under D1316 Pharmacy Services: 13.4 Medications Maintained in the CC shall be appropriately stored and safeguarded against diversion or access by unauthorized persons. Appropriate records shall be kept regarding the disposition of all medications.

To review cited deficiencies associated with this investigation, search the Buena Vista Correctional Complex name at https://cdphe.colorado.gov/find-and-compare-facilities

Thank you for sharing your concerns.

Sincerely,

Jo Tansey

Jo Tansey
Acute Care and Nursing Facilities Branch Chief
Health Facilities and Emergency Medical Services Division

Allegations for: CO00036221 - BUENA VISTA CORRECTIONAL COMPLEX - 05/30/2024-Closed - 703811(08/29/2024)

Pharmaceutical Services-Substantiated

The complainant alleged the facility failed to provide pharmaceutical services in accordance with recognized standards.

The complainant stated the facility failed to ensure patients were monitored after receiving medications to ensure the medications were ingested and not diverted.

Findings:

A regulatory review was completed on 8/29/24. Sixteen patients were included in the sample for this review.

Facility documents were reviewed. Eleven staff members were interviewed. Observations were conducted throughout the facility.

The allegation the facility failed to provide pharmaceutical services within recognized standards and facility policy by ensuring patients were monitored after receiving medications was substantiated.

The facility failed to comply with state regulations pertaining to the subject of the allegation.

Based on observations, interviews, and document review, the facility failed to ensure nursing staff monitored patients receiving medications to prevent diversion and unauthorized access.

The facility was cited with deficient practice under 1316 Pharmacy Services: 13.4 Medications maintained in the CC shall be appropriately stored and safeguarded against diversion or access by unauthorized persons. Appropriate records shall be kept regarding the disposition of all medications.

To review cited deficiencies associated with this investigation, search the Buena Vista Correctional Complex name at https://cdphe.colorado.gov/find-and-compare-facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	180502	A. BUILDING: _____ B. WING _____	C 08/29/2024

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BUENA VISTA CORRECTIONAL COMPLEX	15125 US-24 BUENA VISTA, CO 81211

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C 000	Initial Comments A complaint survey, prompted by #CO36221, was completed on 8/29/24. One deficiency was cited.	C 000		
C1316	9.13.4 RxSvcs Store/Safeguard/Disposition STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER 9 - COMMUNITY CLINICS Part 13. PHARMACY SERVICES 13.4 Medications maintained in the CC shall be appropriately stored and safeguarded against diversion or access by unauthorized persons. Appropriate records shall be kept regarding the disposition of all medications. This STANDARD is not met as evidenced by: Based on observations, interviews, and document review, the facility failed to ensure staff and patients were not permitted unauthorized access to narcotics (a class of drugs that affects the central nervous system including Suboxone, morphine, codeine, and methadone). Findings include: Facility policies: According to the Medication Assisted Treatment (MAT) Program clinical standard, revised 9/2019, all MAT medications will be accounted for and stored in accordance with Clinical Standards and Procedures, Counts-Narcotics, and Sharps. Suboxone administration: nursing will observe the patient for two minutes following administration.	C1316		9/2/24

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C1316	Continued From page 1 According to the Counts - Sharps, Medical Devices, Tools, and Narcotics clinical standard, accountability counts will be completed at the beginning and end of each shift change or scheduled work day with one employee coming on duty and another employee remaining on duty or going off duty. Accountability counts will be documented on the Narcotic and Sharps Count form to verify that the counts were performed and are accurate. The Health Services Administrator (HSA) will review the completed form and sign it verifying that it was reviewed. Narcotics will be stored in a locked cabinet behind a locked door and will be counted at the beginning and end of each clinical services shift change/scheduled work day. Methadone and buprenorphine will be stored in a locked cabinet equipped with an audit trail behind a locked door. At the time of administration, all narcotics must be signed out by two clinical services employees who administer the medications utilizing the controlled substance record issued by the pharmacy. If two clinical services employees are not available, one non-clinical employee may sign the controlled substance record. According to the Medication Management and Accountability clinical standard, nurses or pharmacy technicians have the primary responsibility of managing offender medications. This includes secured storage, perpetual inventory, and maintenance of documentation. Controlled substances will be maintained on a perpetual inventory according to the Counts-Narcotics and Sharps clinical standard. According to the Medication Administration and Documentation clinical standard, documentation of the administered medications will be completed in the electronic medical record (EMR)	C1316		

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immediately after the patient has taken the medication.

According to the Pharmacy Services clinical standard, accountability for administering or distributing medications is performed in a timely manner, according to the prescribing provider's orders.

1. The facility failed to ensure staff and patients were not permitted unauthorized access to Suboxone.

A. Observations

i. On 8/27/24 at 5:00 a.m., observations were conducted in the medication room during a medication pass. Observations revealed nurses administering Suboxone to patients during the morning medication pass. Nurses pulled each patients' Suboxone from baskets. For the patients on a Suboxone tablet, the nurses placed the Suboxone tablet into a medication cup, placed another empty medication cup on top, and crushed the tablets using a metal tool. The medication cup with the crushed tablet was then given to the patients, the patients placed the powder under their tongues, and the nurses checked their mouths for the presence of the powder. For the patients on Suboxone films, the nurses administered the films on the side of their mouths and checked the placement with a flashlight. After verifying placement of the medication with the nursing staff, the patients walked away.

This observation, which did not reveal a wait time, was in contrast to the MAT Program clinical standard which read, nursing staff observed the patient for two minutes following administration.

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C1316	Continued From page 3 B. Document review i. On 8/19/24, a review was conducted of the Narcotics and Sharps Count Form dated 8/14/24 to 8/19/24. The log revealed narcotics and sharps were counted three times daily and each review was signed off by two staff members. ii. On 8/19/24, a review was conducted of the Controlled Substance Records for the patients prescribed buprenorphine/naloxone (Suboxone). a. This review on 8/19/24 of the Controlled Substance Records revealed one patient prescribed Suboxone 8-2 milligram (mg) tablet already had their 8/20/24 (the next day) Suboxone tablets signed off as having been administered by a nurse. This medication sign-off in advance of the medication administration was in contrast to the Medication Administration and Documentation clinical standard which read, documentation of the administered medications was completed in the EMR immediately after the patient took their medication. b. The review of the Controlled Substance Records revealed one patient was missing the time the Suboxone was administered as well as the nurse sign-off on 8/18/24. c. The review of the Controlled Substance Records revealed two different patients were missing the nurse sign-off for Suboxone on 8/13/24. This lack of nursing sign-off was in contrast to the Counts - Sharps, Medical Devices, Tools, and	C1316		

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Narcotics clinical standard which read, at the time of administration, all narcotics were signed out by two clinical services employees who administered the medications utilizing the controlled substance record.

iii. A review was conducted of the Quality Reports which revealed nurses had mistakenly administered Suboxone twice in one day to a patient, once during the morning medication pass at the medication window and another at 12:00 p.m. on the unit.

The lack of documentation in the Controlled Substance Records and the medication error created the potential for misuse or diversion of a narcotic medication by patients and staff which was in contrast to the Medication Management and Accountability clinical standard which read, nurses were responsible for managing patient medications which included secured storage, perpetual inventory, and maintenance of documentation.

C. Interviews

i. On 8/20/24 at 12:06 a.m., an interview was conducted with registered nurse (RN) #1. RN #1 stated Suboxone was a narcotic, however, it was not counted along with the rest of the narcotics. They stated they had counted the narcotics and sharps, excluding the Suboxone, on 8/20/24 and signed off on the narcotic count as a whole.

This was in contrast to the Counts - Sharps, Medical Devices, Tools, and Narcotics clinical standard which read, accountability counts were completed at the beginning and end of shifts. Accountability counts were documented on the Narcotic and Sharps Count form to verify the

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counts were performed and were accurate.

RN #1 stated the Suboxone took longer to count as there were more tablets of this medication than any other and so it was not counted three times daily along with the rest of the narcotics. They stated the narcotic count was important to ensure the controlled medications (medications with the potential for misuse) were accounted for.

RN #1 stated staff occasionally forgot to sign the Controlled Substance Record and if so, they flagged this missing entry for staff to sign at a later date. They stated they had verified on the computer that the patient who was missing a nurse sign-off on 8/18/24 for Suboxone had received their medication although the paper entry was missing the nurse's signature.

This was in contrast to the Counts - Sharps, Medical Devices, Tools, and Narcotics clinical standard which read, at the time of administration, all narcotics were signed out by two clinical services employees who administered the medications utilizing the controlled substance record.

RN #1 stated ensuring medications were accounted for and signed off was important to ensure patients received the medications they were prescribed and to limit the risk of diversion (illegal distribution or misuse of medications).

This interview was in contrast to the Medication Management and Accountability clinical standard which read, nurses were responsible for managing patient medications which included secured storage, perpetual inventory, and maintenance of documentation.

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C1316	Continued From page 6 ii. On 8/20/24 at 9:57 a.m., an interview was conducted with RN Manager (Manager) #3. Manager #3 stated they provided oversight to the clinical staff. They stated Suboxone was prescribed to patients diagnosed with an opioid use disorder (OUD) to prevent them from misusing drugs and potentially overdosing. Manager #3 stated patients were given Suboxone at either 5 a.m. or 12 p.m. each day. Manager #3 stated nurses signed off on the medication administration log at the time of administration but there were times the nurses forgot to sign. They stated nurses were only to sign off when medications were administered as this could impact their ability to retain their license. Manager #3 stated if patients did not receive their Suboxone as prescribed, for example, the patients who did not have an administration charted on 8/18/24 or the patient who had their medication pre-charted for 8/20/24 and could potentially be missing their medication, they may become dizzy, nauseous, or have headaches. Manager #3 stated Suboxone was counted with the other narcotics three times daily. This was in contrast to the interview with RN #1 who stated they participated in the narcotic count and did not count Suboxone. Manager #3 stated the Suboxone count for 8/20/24 had been correct. They stated that on 8/19/24 with one patient's Suboxone already charted as given for 8/20/24, the Suboxone count was correct as the nurses utilized critical thinking to work through discrepancies. Manager #3 stated Suboxone counts were important to hold staff accountable. They stated if Suboxone was diverted by staff or patients, there	C1316		

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was a risk of addiction to the persons inappropriately using the medication as well as an infection control risk if the medication was stored and transported in an unhygienic fashion.

This interview was in contrast to the Medication Management and Accountability clinical standard which read, nurses were responsible for managing patient medications which included secured storage, perpetual inventory, and maintenance of documentation.

iii. On 8/20/24 at 1:56 p.m., an interview was conducted with RN Manager (Manager) #4. RN Manager #4 stated they also provided oversight to the other clinical staff. They stated Suboxone was counted at night and sometimes in the mornings while other narcotics were counted three times daily. Manager #4 stated there was no way to differentiate on the Narcotics and Sharps Count Form when Suboxone was included in the narcotic count.

This lack of consistency in accounting for the total amount of Suboxone was in contrast to the Counts - Sharps, Medical Devices, Tools, and Narcotics clinical standard which read, accountability counts were completed at the beginning and end of shifts. Accountability counts were documented on the Narcotic and Sharps Count form to verify the counts were performed and were accurate.

Manager #4 stated the Suboxone program had grown recently and they did not have the appropriate staffing to handle their current responsibilities. They stated the nurse managers and health services administrator (Administrator) #6 were responsible for auditing the Suboxone counts every week. Manager #4 stated they

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co-signed the Narcotic and Sharps Count Form when they had audited the Suboxone. However, Manager #3 stated they also participated in counting and signing off on the narcotics and sharps at times when the Suboxone was not counted, so their sign-off did not mean the Suboxone was audited. They stated there was no way to know from the Narcotics and Sharps Count Form when the Suboxone was last counted or audited.

This lack of consistency in accounting for the total amount of Suboxone was in contrast to the Counts - Sharps, Medical Devices, Tools, and Narcotics clinical standard which read, accountability counts were completed at the beginning and end of shifts. Accountability counts were documented on the Narcotic and Sharps Count form to verify the counts were performed and were accurate.

Manager #4 stated the risk of not accounting for the Suboxone, along with gaps in the Controlled Substance Records, created a risk for theft or diversion.

This interview was in contrast to the Medication Management and Accountability clinical standard which read, nurses were responsible for managing patient medications which included secured storage, perpetual inventory, and maintenance of documentation.

iv. On 8/20/24 at 11:27 a.m., an interview was conducted with Administrator #6. Administrator #6 stated they provided oversight to the clinical program to ensure quality patient care. They stated they trusted all of the staff and felt any gap in documenting medications was the result of a mistake.

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C1316	Continued From page 9 v. On 8/21/24 at 1:59 p.m., an interview was conducted with medical doctor (Provider) #9. Provider #9 stated they oversaw the MAT program. They stated clinical staff had been working off a MAT Program clinical standard from 2019. Provider #9 stated Suboxone was a treatment for OUD. They stated Suboxone helped decrease cravings for opioids, reduce illicit (unauthorized) drug use, and reduce the risk of human immunodeficiency virus (HIV) (a virus that impacts the immune system), Hepatitis C (a virus that causes liver damage), and overdose. Provider #9 stated they were aware patients were diverting substances within the facility, including Suboxone. They stated, however, that not all drugs came from their pharmacy as some drugs were brought into the facility. Provider #9 stated they required clinical staff to perform mouth checks after the Suboxone was given. However, they did not mandate a wait time for sublingual (under the tongue) absorption as this was not required at other similar facilities. Provider #9 stated the monitored wait time of two minutes after Suboxone administration, as specified in the 2019 MAT Program clinical standard, could not be met as the facility was required to expand the MAT program to more eligible patients. Provider #9 stated they had revised the clinical standard for the MAT program to meet the current practice, guidelines, and expectations, and the staff would have access to the revised standard shortly. Provider #9 stated there was a high patient demand for Suboxone and little supply. Provider #9 stated the facility prevented patient diversion of Suboxone by increasing overall access to OUD	C1316		

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C1316	Continued From page 10 medications. They stated Suboxone helped patients overcome addiction and it was important for the facility to provide Suboxone to as many eligible patients as possible to reduce misuse and save lives. Provider #9 stated patients always diverted and misused medications and illegal substances and it was not possible to eliminate diversion.	C1316		