

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL034-303</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>05/04/2021</b>
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NAME OF PROVIDER OR SUPPLIER  <b>SHARPE AND WILLIAMS #2</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>4408 NORTHAMPTON DRIVE WINSTON-SALEM, NC 27105</b>
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V 000	<p>INITIAL COMMENTS</p> <p>An annual and complaint survey was completed on 5/4/2021. The complaint was unsubstantiated (intake #NC176169). Deficiencies were cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .5600A Supervised Living for Adults with Mental Illness.</p>	V 000		
V 118	<p>27G .0209 (C) Medication Requirements</p> <p>10A NCAC 27G .0209 MEDICATION REQUIREMENTS</p> <p>(c) Medication administration:</p> <p>(1) Prescription or non-prescription drugs shall only be administered to a client on the written order of a person authorized by law to prescribe drugs.</p> <p>(2) Medications shall be self-administered by clients only when authorized in writing by the client's physician.</p> <p>(3) Medications, including injections, shall be administered only by licensed persons, or by unlicensed persons trained by a registered nurse, pharmacist or other legally qualified person and privileged to prepare and administer medications.</p> <p>(4) A Medication Administration Record (MAR) of all drugs administered to each client must be kept current. Medications administered shall be recorded immediately after administration. The MAR is to include the following:</p> <p>(A) client's name;</p> <p>(B) name, strength, and quantity of the drug;</p> <p>(C) instructions for administering the drug;</p> <p>(D) date and time the drug is administered; and</p> <p>(E) name or initials of person administering the drug.</p> <p>(5) Client requests for medication changes or checks shall be recorded and kept with the MAR file followed up by appointment or consultation</p>	V 118		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ (X6) DATE \_\_\_\_\_

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V 118	<p>Continued From page 1</p> <p>with a physician.</p> <p>This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure that medications were only administered on the written order of an authorized person affecting 1 of 1 deceased client (DC #4). The findings are:</p> <p>Reviews on 4/14/2021, 4/15/2021 and 4/19/2021 of DC #4's record revealed:</p> <ul style="list-style-type: none"> <li>- Admission date: 4/16/2014</li> <li>- Date of death: 3/22/2021</li> <li>- Diagnoses: Schizophrenia, Tachycardia, Constipation, Hypertriglyceridemia, Solid Cystic Pseudopapillary Tumor of Pancreas, Non-rheumatic aortic valve insufficiency, Chronic fatigue, Essential hypertension.</li> <li>- Documentation of examination by a Cardiologist on 9/24/2020, with follow up recommended in two years.</li> <li>- Documentation of medication management visits with an area Behavioral Health Agency (BHA) Nurse Practitioner (BHA-NP) on 11/4/2020 and 2/5/2021.</li> <li>- Documentation of examinations by an Adult Gerontology Nurse Practitioner-Board Certified (AGNP-BC) monthly from 11/16/2020 to 3/15/2021.</li> <li>- Documentation of laboratory bloodwork (labs) results completed monthly from 10/9/2020 to 2/19/2020.</li> <li>- The 2/19/2021 labs revealed white blood count (WBC) and absolute neutrophil levels within the</li> </ul>	V 118		

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V 118	<p>Continued From page 2</p> <p>test "reference range."</p> <ul style="list-style-type: none"> <li>- Medication orders for the following:               <ul style="list-style-type: none"> <li>-- Clozapine 100 milligrams (mg), 1 tablet (tab) every morning and 2 tablets at bedtime, original order dated 1/8/2019;</li> <li>-- On the FL2 form dated 10/21/2020: "Clozapine 100mg (milligrams) 1-Tab (tablet) Mornings"; and "Clozapine 100mg 2-Tabs Evenings"</li> <li>-- Clozapine 100 mg disintegrating tablets, "Take 3 tablets by oral route per daily 1 tab under tongue in the AM and 2 tabs at bedtime (QHS), Only release 30 days at a time after, confirmation of lab results," dated 11/4/2020.</li> </ul> </li> </ul> <p>Review on 4/23/2021 of DC #4's autopsy report revealed:</p> <ul style="list-style-type: none"> <li>- The autopsy was completed on 3/24/2021.</li> <li>- "... Final Summary: ...After review of the decedent's past medical and social history, the findings at autopsy, and toxicology examination, it is the opinion of the prosecutor that the decedent, [DC #4], died as a result of a combination of natural causes including severe coronary artery disease, severe aortic stenosis with infectious endocarditis, and acute bilateral bacterial pneumonia. The elevated level of clozapine may be contributory. The manner of death is natural."</li> </ul> <p>Reviews on 4/19/2021, 4/20/2021 and 4/21/2021 of DC #4's MARs dated 10/1/2020 to 3/22/2021 revealed:</p> <ul style="list-style-type: none"> <li>- The MARs were documented in an electronic medication chart system.</li> <li>- The administration instruction for the 8:00AM dose of clozapine was "100/ODT, 1 SL (sublingually) for See Patient's diagnosis, Take 1 TABLET (100MG) SUBLINGUALLY EVERY MORNING ..." on the 10/1/2020 to 11/3/2020 MARs.</li> <li>- On 11/4/2020, the administrations instruction for</li> </ul>	V 118		

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V 118	<p>Continued From page 3</p> <p>the 8:00AM dose of clozapine increased to "100/ODT, 3 SL for See Patient's diagnosis, Take 3 TABLETS (300MG) SUBLINGUALLY EVERY MORNING ..."</p> <ul style="list-style-type: none"> <li>- The 8:00AM dose of clozapine was documented as having been administered as per the instructions every morning.</li> <li>- The administration instructions for the "20:00" (8:00PM) dose of clozapine remained unchanged as "100/ODT, 2 SL for See Patient's diagnosis, Take 2 TABLETS (200MG) SUBLINGUALLY AT BEDTIME ..." from 10/1/2020 through 3/22/2021.</li> </ul> <p>Review on 5/3/2021 of photographs of DC #4's medication bubble packs revealed:</p> <ul style="list-style-type: none"> <li>- A bubble pack with 3 tablets in each bubble was filled on 2/8/2021.</li> <li>- A bubble pack with 2 tablets in each bubble was filled on 3/19/2021.</li> <li>- Medication label instructions on both were: Clozapine Tab 100/ODT, "Take 3 tablets (300MG) sublingually every morning; Take 2 tablets (200MG) sublingually at bedtime."</li> </ul> <p>Interviews from 4/19/2021 to 4/23/2021 with DC #4's Guardian revealed:</p> <ul style="list-style-type: none"> <li>- He had picked DC #4 up for a home visit the day before his death.</li> <li>- He had not been able to visit DC #4 in approximately one year due to the Covid-19 crisis.</li> <li>- The Pathologist that completed the autopsy had told him that DC #4 had bacterial pneumonia in both lungs, his clozapine level was 3 or 4 times higher than it should have been, and that the clozapine level may have contributed to DC #4's death.</li> <li>- DC #4 was seen at the BHA every three months in order to treat his schizophrenia.</li> <li>- A blood test was completed every month and</li> </ul>	V 118		

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V 118	<p>Continued From page 4</p> <p>sent to the BHA and the Pharmacy.</p> <ul style="list-style-type: none"> <li>- The Pharmacy would not refill DC #4's clozapine until the blood test was reviewed.</li> <li>- The facility had an electronic medication system for several years.</li> <li>- He did not believe the facility did anything out of order with DC #4's medications intentionally.</li> <li>- D C #4 had done well at the facility, but he did not know how his clozapine level had increased.</li> <li>- He just needed to understand what had happened to cause DC #4's death.</li> </ul> <p>Interview on 4/27/2021 with the AGNP-BC revealed:</p> <ul style="list-style-type: none"> <li>- When she had examined DC #4 on 3/15/2021, his lungs were clear, his oxygen saturation level was good, and he did not have a fever.</li> <li>- She listened to DC #4's lung sounds and carotid (carotid artery pulse in neck) sounds at every visit.</li> <li>- She did not prescribe DC #4's clozapine.</li> <li>- DC #4 had lab work completed every month.</li> <li>- DC #4's February 2021 lab results had revealed that his white blood count was normal, his kidney function was great, and had not indicated anything that she was concerned about.</li> <li>- It was not standard practice to test the clozapine level every month.</li> <li>- The lab result that was most relevant to monitor for people taking clozapine was the white blood count because clozapine could cause a blood disorder that makes it harder for the body to fight infections.</li> <li>- She reviewed DC #4's MARs at every visit.</li> <li>- It had looked like DC #4 had been taking all of his medications as prescribed.</li> <li>- She thought that DC #4 had been well cared for at the facility.</li> </ul> <p>Interview on 4/28/2021 with the BHA Registered</p>	V 118		

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V 118	<p>Continued From page 5</p> <p>Nurse (BHA-RN) revealed:</p> <ul style="list-style-type: none"> <li>- She was the nurse that assisted the BHA-NP with client appointments.</li> <li>- The BHA-NP prescribed DC #4's clozapine.</li> <li>- DC #4's dose of clozapine had not changed in November of 2020.</li> <li>- The prescribed clozapine dose was for 100mg, 1 tablet in the morning and 2 tablets at bedtime.</li> <li>- Lab work was drawn for DC #4 every month.</li> <li>- It was not necessary to check the clozapine level routinely because the most important level to check related to clozapine was the neutrophils.</li> <li>- The Pharmacy would review the lab results before they refilled DC #4's clozapine every month.</li> <li>- The Pharmacy would not refill the clozapine if the lab results were "off."</li> </ul> <p>Interview on 4/26/2021 with the Pharmacy Staff revealed:</p> <ul style="list-style-type: none"> <li>- DC #4's lab results were monitored monthly due to his clozapine prescription.</li> <li>- The most relevant lab results related to clozapine use were the white blood count (WBC) and the absolute neutrophils, with the absolute neutrophils requiring the most scrutiny.</li> <li>- DC #4's absolute neutrophil level on the 2/23/2021 lab results had been "fine."</li> <li>- The clozapine order that the Pharmacy had was for 300mg in the morning and 200mg at bedtime for a total of 500mg every day.</li> <li>- That order dated back to 11/4/2020.</li> <li>- When the Pharmacy received electronic medication orders, they keyed the order into an electronic medication system.</li> <li>- DC #4's clozapine was refilled every 28 days.</li> <li>- The last refill of clozapine had been dispensed on 3/8/2021 for 300mg in the morning and 200mg at bedtime.</li> </ul>	V 118		

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V 118	<p>Continued From page 6</p> <p>Interviews on 4/14/2021 and 4/29/2021 with staff #1 revealed:</p> <ul style="list-style-type: none"> <li>- He had been working on the evening before and the morning of DC #4's death on 3/22/2021.</li> <li>- On 3/21/2021, DC #4 had left the facility on a home visit with his Guardian.</li> <li>- When DC #4 had returned to the facility following his visit with family, he had gone straight to his bedroom to lie down, stating that he was "hurting."</li> <li>- The next morning, DC #4 was not acting as he normally did, was having trouble breathing, and was not responding to staff #1.</li> <li>- Staff #1 called emergency medical services (EMS) but DC #4 stopped breathing just before EMS arrived.</li> <li>- He was not aware of any issues with medication administration or MARs.</li> <li>- If he found any issues with medications or MARs, he would call the Medication Supervisor.</li> </ul> <p>Interviews on 4/20/2021 and 4/29/2021 with the Qualified Professional (QP) #1 revealed:</p> <ul style="list-style-type: none"> <li>- She had been DC #4's QP since November of 2020.</li> <li>- DC #4 had medical appointments with the AGNP-BC at the facility every month, and at the BHA with the BHA-NP every three months.</li> <li>- She attended DC #4's psychiatric appointments with the BHA-NP on 11/4/2020 and 2/5/2021.</li> <li>- DC #4's clozapine morning dose had not been changed since she became his QP.</li> <li>- During the 11/4/2020 appointment with the BHA-NP, she (the BHA-NP) had told DC #4 that she was not going to change any of his medications because he seemed to be doing "well."</li> <li>- She had not seen the change from 1 tablet of clozapine to 3 tablets of clozapine every morning on DC #4's MARs.</li> </ul>	V 118		

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V 118	<p>Continued From page 7</p> <ul style="list-style-type: none"> <li>- Because he was taking clozapine, DC #4 had labs completed every month.</li> <li>- The Pharmacy and the BHA-NP specifically reviewed DC #4's white and red blood counts on the CBC (complete blood count) with differentials lab results to monitor the clozapine.</li> <li>- There had not been any concerns raised about DC #4's lab results due to his clozapine use.</li> <li>- When medication doses were changed, the Pharmacy received electronic orders and entered the information into an electronic medication chart system.</li> <li>- The MARs used by the facility were the ones in the electronic medication chart system.</li> <li>- There had been times in the past in which the Pharmacy had a medication order that was different than the one the facility had.</li> <li>- When the MAR did not match the order, facility staff would contact the Nurse or Doctor at the prescribing agency.</li> </ul> <p>Interviews on 4/30/2021 and 5/3/2021 with the Medication Supervisor revealed:</p> <ul style="list-style-type: none"> <li>- She had been working as the Medication Supervisor since approximately November of 2020.</li> <li>- When medication orders were written, a copy was sent to the Pharmacy.</li> <li>- The Pharmacy entered the medication administration instructions into the electronic medication chart system.</li> <li>- She always matched the medication order up to the electronic MAR to ensure that the MAR was correct.</li> <li>- DC #4 had not had any changes to his morning clozapine dose.</li> <li>- DC #4 had labs drawn every month in order to monitor his clozapine.</li> <li>- The lab results were sent to everyone involved with DC #4's care.</li> </ul>	V 118		



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V 118	<p>Continued From page 8</p> <ul style="list-style-type: none"> <li>- There had not been any concerns raised about DC #4's lab results related to his clozapine dose.</li> <li>- After reviewing DC #4's MARs from November 2020 through March 2021, it looked like the morning dose of clozapine was a misprint.</li> <li>- She did not know how DC #4's morning clozapine dosage had changed without having a new order for the dose increase.</li> <li>- The order that she saw in the facility's electronic system was for 3 clozapine tablets in the morning and 2 at night.</li> <li>- She matched new medication orders up with the MARs in the electronic medication chart system, but she was confused about how DC #4's morning clozapine dose changed.</li> </ul> <p>Interviews with the Director from 4/13/2021 to 5/4/2021 revealed:</p> <ul style="list-style-type: none"> <li>- The facility's electronic MAR system was integrated with the Pharmacy's system.</li> <li>- The Pharmacy entered medication administration dosages and instructions into the MARs used by the facility.</li> <li>- She had spoken to the Pharmacy and they confirmed that they had entered DC #4's clozapine dose incorrectly in the electronic medication system.</li> <li>- DC #4 had lab work monitored monthly.</li> <li>- The Pharmacy had to enter DC #4's neutrophil levels into an electronic database before they could refill it.</li> <li>- Because DC #4's lab results had not changed, there had been nothing to alert the Pharmacy that there were any issues with his clozapine dose.</li> <li>- She and the Medication Supervisor reviewed medication orders monthly.</li> <li>- They tried to check behind the Pharmacy to check for MAR accuracy.</li> <li>- She did not know how DC #4's incorrect morning dose of clozapine was missed.</li> </ul>	V 118		

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V 118	<p>Continued From page 9</p> <p>Review on 5/4/2021 of the Plan of Protection dated 5/3/2021 written by the Director revealed:</p> <ul style="list-style-type: none"> <li>- What immediate action will the facility take to ensure the safety of the consumers in your care?</li> </ul> <p>"The immediate action that will take place at the facility to ensure the safety of the consumers in care will be the following;</p> <ul style="list-style-type: none"> <li>- Suspend medication supervisor medication approval access at this time, and only allow administrative director to approve orders.</li> <li>- Collaborate with [the Pharmacy] to understand the process of transcription of medications onto the MAR. All MARS will continue to be checked on a monthly basis and ensure all orders are appropriately attached to the prescribed medication and all orders match what is in the system. Continue to communicate on an ongoing basis any discrepancy found with orders with prescribing provider and pharmacy.</li> <li>- No medication will be given without written order from provider, per already stated policy."</li> <li>- Describe your plans to make sure the above happens.</li> </ul> <p>"To ensure the above actions mentioned are taken into consideration this will be the timeline for the actions mentioned above effective 5/3/21-5/4/20.</p> <ul style="list-style-type: none"> <li>- The administrative staff will suspend access to chartmeds system to medication supervisor role and only administrator (the Director) will approve medications.</li> <li>- The administrator will correspond with [the Pharmacy] to initiate and understand transcription protocols.</li> <li>- All MARS will continue to be checked on a monthly basis at the monthly administrative meetings."</li> </ul> <p>This deficiency was cited as a standard level</p>	V 118		

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V 118	Continued From page 10  deficiency during the survey completed 3/10/2021, but evidence in this survey has increased the severity of this deficiency.  DC #4 had a history of schizophrenia and multiple medical disorders, combined with long-term treatment with the anti-psychotic medication, clozapine. Close monitoring of laboratory results was required due to the potential of serious adverse effects of clozapine. DC #4's clozapine dose had been 100mg every morning and 200mg at bedtime and remained unchanged since at least 1/8/2019. On 11/4/2020, due to a keying error in the electronic medication record system, the wrong dose of clozapine was listed on DC #4's MAR. This resulted in facility staff administering 300mg instead of the prescribed 100mg every morning. The facility had processes in place to monitor MAR accuracy but did not identify the error with DC #4's morning clozapine dose prior to his death on 3/22/2021. This deficiency constitutes a Type A1 rule violation for serious neglect and must be corrected within 23 days. An administrative penalty of \$5,000.00 is imposed. If the violation is not corrected within 23 days, an additional administrative penalty of \$500.00 per day will be imposed for each day the facility is out of compliance beyond the 23rd day.	V 118		
V 736	27G .0303(c) Facility and Grounds Maintenance  10A NCAC 27G .0303 LOCATION AND EXTERIOR REQUIREMENTS (c) Each facility and its grounds shall be maintained in a safe, clean, attractive and orderly manner and shall be kept free from offensive odor.	V 736		

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL034-303</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>05/04/2021</b>
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NAME OF PROVIDER OR SUPPLIER  <b>SHARPE AND WILLIAMS #2</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>4408 NORTHAMPTON DRIVE WINSTON-SALEM, NC 27105</b>
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V 736	<p>Continued From page 11</p> <p>This Rule is not met as evidenced by: Based on observations and interviews, the facility was not maintained in a safe, clean, attractive and orderly manner, and free of offensive odors. The findings are:</p> <p>Observations from approximately 2:55pm to 3:40pm on 4/13/2021 of the facility revealed:</p> <ul style="list-style-type: none"> <li>- Client's #1 and #3's bedroom floor had stains on the carpet.</li> <li>- Client #1's bed frame was broken.</li> <li>- In the laundry alcove, lint clung to the wall behind the dryer, and clothing items were on the floor between the dryer and the wall.</li> <li>- The bedroom belonging to a client that was not audited was cluttered, had stains on the carpet, and had a smoke detector that was beeping periodically.</li> <li>- Client #2's bed had a platform frame instead of a box spring base.</li> <li>- The platform frame did not fit the base, causing the bed to wobble.</li> <li>- The vertical blind was broken at the top, causing it to fall when touched.</li> <li>- A strong odor of feces was present in the bedroom.</li> <li>- The client bathroom, accessible through client #2's bedroom, had feces in the toilet.</li> <li>- The ceramic-type floor tiles in the bathroom had crumbling grout, 2 tiles were cracked/broken, and multiple tiles were loose.</li> <li>- The floor of the shower had cracks present.</li> <li>- The bedroom that had been deceased client (DC) #4's had stains on the carpet.</li> <li>- The ceramic-type floor tiles in the kitchen had missing grout, 14 tiles were cracked/broken, and multiple tiles were loose.</li> </ul>	V 736		

Division of Health Service Regulation

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V 736	<p>Continued From page 12</p> <p>Observation at approximately 10:30am on 4/15/2021 revealed:</p> <ul style="list-style-type: none"> <li>- A brown stain was present on the kitchen ceiling covering an area approximately 2-1/2 feet by 1 foot.</li> </ul> <p>Interview on 4/13/2021 with client #2 revealed:</p> <ul style="list-style-type: none"> <li>- His bed was uncomfortable to sleep on because the "rails" (platform frame) did not fit the floor frame.</li> <li>- His previous bed frame "just fell apart."</li> <li>- He had talked to Qualified Professional (QP) #2 and his Guardian about his bed approximately 2-3 months ago.</li> <li>- He had been told that he had to pay \$100 to purchase a new bed frame.</li> <li>- Water leaked into the base of the shower floor because there were cracks in it.</li> </ul> <p>Interview on 4/13/2021 with client #3 revealed:</p> <ul style="list-style-type: none"> <li>- The tiles in the kitchen were loose because they were old and walked on several times every day.</li> <li>- He had not paid any attention to the loose tiles in the bathroom.</li> </ul> <p>Interview on 4/14/2021 with staff #1 revealed:</p> <ul style="list-style-type: none"> <li>- The floor tiles in the bathroom and kitchen had been there since he started work at the facility 1-1/2 months ago.</li> <li>- He was not sure if client #2 had broken his bed or had been trying to fit it, but he had complained that something was wrong with it 2-3 weeks ago.</li> <li>- He thought that client #2 had been told that he needed to purchase a new bed rail with his own money because he had thrown out his old rail and dragged in another one that he had found outside.</li> <li>- Client #2 had talked to QP #2 about the bed.</li> <li>- The stain on the kitchen ceiling looked like it</li> </ul>	V 736		

Division of Health Service Regulation

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V 736	<p>Continued From page 13</p> <p>was caused by a leak.</p> <ul style="list-style-type: none"> <li>- He was not aware of any leaks in the kitchen since he was hired.</li> <li>- When repairs needed to be made at the facility, facility staff were supposed to post the information to an electronic system used for all documentation, and the repairs would be handled by maintenance staff.</li> </ul> <p>Interview on 4/16/2021 with QP #2 revealed:</p> <ul style="list-style-type: none"> <li>- At an unknow time, client #2 had thrown out his box springs and then dragged in the platform frame that was currently on his bed.</li> <li>- The platform frame had been discarded by someone else.</li> <li>- A new bed frame had already been ordered for client #2 but had not yet arrived.</li> <li>- Client #2 had not informed him that he was uncomfortable with his bed before he threw out his old box spring.</li> <li>- New beds were purchased for client #3 periodically because he broke them.</li> <li>- It was a team effort to ensure the facility was kept in good condition.</li> </ul> <p>Interview on 5/4/2021 with the Director revealed:</p> <ul style="list-style-type: none"> <li>- Mattresses and box springs have been replaced since the date of the Surveyor's observation.</li> <li>- The floor tiles had not been loose at that time.</li> <li>- There had not been any water leaks above the kitchen ceiling.</li> <li>- She had talked to the building owner about repairing the smoke detector that was beeping.</li> <li>- In November of 2020, carpet cleaning and repair work had been completed at the facility.</li> <li>- She believed that most of the items identified by the Division of Health Service Regulation (DHSR) Construction Section on 3/10/2020 had been corrected.</li> </ul>	V 736		