

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  CA010000066	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____		(X3) DATE SURVEY COMPLETED  05/23/2016
NAME OF PROVIDER OR SUPPLIER  BROADWAY VILLA POST ACUTE		STREET ADDRESS, CITY, STATE, ZIP CODE 1250 BROADWAY SONOMA, CA 95476			
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B 000	Initial Comments  The following reflects the findings of the California Department of Public Health during an ANNUAL RELICENSURE SURVEY.  Representing the California Department of Public Health: Health Facilities Evaluator Nurses 28522, 29092, 31424, and 34336  The facility census on the day of entry, 5/16/16 was 122 with one bedhold.  There were 8 sampled residents	B 000			
B2030	T22 DIV5 CH3 ART3-72369(b) Pharmaceutical Service--Controlled Drugs  (b) Separate records of use shall be maintained on all Schedule II drugs. Such records shall be maintained accurately and shall include the name of the patient, the prescription number, the drug name, strength and dose administered, the date and time of administration and the signature of the person administering the drug. Such records shall be reconciled at least daily and shall be retained at least one year. If such drugs are supplied on a scheduled basis as part of a unit dose medication system, such records need not be maintained separately.  This Statute is not met as evidenced by: Based on interview and record review the facility failed to ensure Schedule II controlled medications (medications identified by the Controlled Substance Act as subject to abuse) located in the automated drug delivery system (ADC) were reconciled on a daily basis. This failures had potential for prescription medications to be diverted, (used for recreational purposes)	B2030	<u>Corrective action for residents found to have been affected by this deficiency:</u>  No specific resident was identified.  <u>Corrective action for residents that may be affected by this deficiency:</u>  All residents have the potential to be affected.  The policy and procedure for narcotic count for the Cubex machine was reviewed and revised on 6/23/16. The new policy states that the Cubex authorization form for narcotic use will be used any time that it is accessed for narcotic medications. Two licensed nurses will sign and witness any time narcotic medication is dispensed from the machine.  The lead nurse will be responsible to conduct a daily count of the controlled substances in the Cubex machine. The daily report of the controlled substance count will also be sent from the pharmacy Cubex administration to the facility. This will be used to reconcile the physical count done by the lead nurse.	6/29/16	

Licensing and Certification Division  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM

6899

K9W011

TITLE

Administrator

(X6) DATE

6/29/16

if continuation sheet 1 of 7

6/29/16 @ 1:28 pm Accepted - E. Olsen RN HFEN  
Notified Eric Olsen (Administrator) via T.C.



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B2030	<p>Continued From page 1</p> <p>by staff.</p> <p>Findings:</p> <p>Review of the Cubex ADC inventory list (dated 5/19/16) indicated it contained controlled medications which included the following Schedule II narcotic pain medications Oxycontin, Dilaudid, Morphine, Methadone, Oxycodone, Hydrocodone.</p> <p>During an interview, on 5/18/16 at 2:50 p.m., the Director of Nursing (DON) stated the controlled medication in the ADC did not need to be counted by licensed staff because they were audited monthly by the pharmacist.</p> <p>During an interview, on 5/23/16 at 1:00 p.m., Pharmacist I stated the pharmacy tracked utilization of controlled medication in the ADC remotely (via computer access). She stated she inspected the ADC monthly and counted the controlled medications at that time.</p> <p>Review of Cubex policy titled "Resolving Discrepancies," subtitled, "Automated Medication Storage Cabinet" (dated 12/31/13) revealed the discrepancies are researched and resolved in accordance to all state and federal regulations. The policy titled, "Narcotic Count" (revised 11/2015) did not specify procedures how or when controlled medication in the ADC would be monitored for accuracy and potential diversion.</p>	B2030	<p><u>Measures that will be put into place to ensure that this deficiency does not recur:</u></p> <p>All licensed staff have been in-serviced on this new policy and procedure for accessing narcotics in the Cubex machine on 6/23/16 by the Director of Staff Development.</p> <p>A log will be created by the DON to verify that the daily count of the controlled substances is completed and reconciled using the pharmacy Cubex daily report. Any discrepancies found during the reconciliation process will be reported immediately to the DON.</p> <p><u>Measures that will be implemented to monitor the continued effectiveness of the corrective action taken to ensure that this deficiency has been corrected and will not recur:</u></p> <p>The pharmacy consultant will conduct a monthly audit of the Cubex narcotic use. She will keep a log of the audits and bring this to the QA&amp;A committee on a quarterly basis. If any discrepancies are found in the narcotic count during this audit she will notify the DON immediately. The QA&amp;A committee will review the log for accuracy. If any the audit shows any inaccuracy in the count the committee will make new recommendations and the results will be reported back to the QA&amp;A.</p> <p>The log of the daily controlled substance count for the Cubex will be brought to the QA&amp;A committee for review. The QA&amp;A committee will review the log for accuracy. If any the audit shows any inaccuracy in the count the committee will make new recommendations and the results will be reported back to the QA&amp;A.</p>		6/29/16
A 016	<p>HSC 1261.6(d)(1) HSC Section 1261</p> <p>(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy,</p>	A 016			

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A 016	<p>Continued From page 2</p> <p>accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.</p> <p>This Statute is not met as evidenced by: Based on interview and record review, the facility did not have specific policies and procedures to ensure: 1. Medication was stored per manufacture's guidelines, which could lead to loss of medication stability and quality, and 2. Accuracy of the emergency supply of controlled medication (drugs subject to abuse) located in the automated drug delivery system (ADC). This failure had potential for prescription medication to be diverted (used for recreational purpose) by staff.</p> <p>Findings:</p> <p>1. During an observation and interview on 5/18/16 at 10:00 a.m., the North medication room thermometer indicated the room was 78°F. Licensed Nurse M confirmed the room temperature.</p> <p>During an observation and interview, on 5/18/16 at 2:35 p.m., the medication room thermometer indicated the room temperature had increased to 80°F (Fahrenheit). Licensed Nurse N confirmed the room temperature.</p> <p>During an observation and interview, on 5/23/16 at 1:45 p.m., the North medication room thermometer indicated the room was 83-84°F. Licensed Nurse B stated she thought the temperature reading was 83°F.</p>	A 016	<p><u>Corrective action for residents found to have been affected by this deficiency:</u></p> <p>1. All medications with manufacturer recommendations for storage not to go over 77 degrees Fahrenheit were discarded so that no residents were affected by this deficient practice.</p> <p>2. The policy and procedure for "Resolving discrepancies – Automated Medication Storage Cabinet" was reviewed and revised by the IDT team in June of 2016. The new policy was changed to indicate that the lead nurse will be responsible to conduct a daily count of the controlled substances in the Cubex machine. The daily report of the controlled substance count will also be sent from the pharmacy Cubex administration to the facility. This will be used to reconcile the physical count done by the lead nurse. A log will be created by the DON to verify that the daily count of the controlled substances is completed and reconciled using the pharmacy Cubex daily report. Any discrepancies found during the reconciliation process will be reported immediately to the DON.</p>		6/29/16

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A016	<p>Continued From page 3</p> <p>During an observation and interview, on 5/18/16 at 10:00 a.m., the North medication room contained multiple medications. Over thirty vials of Heparin (blood thinner medication) were located on a shelf. The manufacturer guidelines document to store Heparin between 68 to 77 degrees F. Review of the Cubex Cabinet (automatic dispensing cabinet or ADC - medication storage unit) inventory list indicated it contained over six hundred doses of various medications. Numerous emergency kits located in the North medication room contained multiple pills and IV (Intravenous) medications. License Nurse N stated some of the medication was overflow medication belonging to residents.</p> <p>During an observation and interview, on 5/20/16 at 4:25 p.m., various medication labels were inspected in the North medication room. Random Resident 31's Depakote (an anti-seizure medication) package indicated to keep in a, "cool dry place." Random Resident 33's Lactulose package indicated to store between 68-77°F (Lactulose is used to treat confusion, altered level of consciousness, and coma resulting from liver failure). Resident 7's Spiriva (asthma/wheezing medication) indicated to store at 77°F. The package indicated excursions were permitted to 59-86°F (Excursions are temperatures outside the range prescribed for storage, allowed for a limited time- for example, during transport of drug). A box of thirty Albuterol vials (asthma/wheezing medication) indicated to store between 36-77°F. Random Resident 34's Clindamycin (antibiotic) package indicated to store between 68-77°F. Thirty Lidocaine patches (for pain) indicated to store between 68-77°F. Licensed Nurse O confirmed these manufacture's storage temperature requirements.</p>	A016	<p><u>Corrective action for residents that may be affected by this deficiency:</u></p> <p>1. All medications with manufacturer recommendations for storage not to go over 77 degrees Fahrenheit were discarded so that no residents were affected by this deficient practice.</p> <p>2. This new Policy and Procedure will be in-serviced to the lead nurses who will carry out the daily count on 6/28/16 by the DON and the Cubex consultant.</p> <p><u>Measures that will be put into place to ensure that this deficiency does not recur:</u></p> <p>1. An inspection done by construction architect on 5/10/16. It was discovered that the north station med room, has two supply registers. One is connected to unit 6. The other register is not connected above the ceiling. The attic heat can travel into the room through this vent. This has been capped by the Maintenance director on 6/14/16. A new medication cart was delivered to the facility on 6/14/16. Medications that need to be stored under 77 degrees are now being kept in this cart which is locked and kept in the hall in front of the north nursing station.</p> <p>Also, plans will be submitted to OSHPD on 6/20/16 to begin the installation of a dedicated air conditioning unit in the two med-rooms of the facility. This will have its own thermostat to individually control the temperature of these rooms.</p>	6/29/16

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A016	<p>Continued From page 4</p> <p>During an interview with the Maintenance Director, on 5/23/16 at 12:30 p.m., he stated he checked the medication room air temperatures daily, in the morning. He stated he did not check the temperatures in the afternoon. Review of facility medication room temperature logs titled, "Ambient Air Checks", indicated the morning air temperatures were higher than manufacture's requirements for medication storage. Between 4/7/16 and 5/20/16, the North medication room temperature was greater than 77°F on five occasions. The log indicated the South medication room temperatures between 9/30/15 and 11/4/15 were 78-80°F on ten occasions. During the same time period, the temperatures in the North medication room were 78-80°F on fifteen occasions. The log indicated the North medication room temperatures between 6/13/15 and 7/14/15 were 79-81°F on five occasions.</p> <p>During a interview on 5/23/16 at 1:00 p.m., Pharmacist I stated medications should be stored per manufacture's recommendations.</p> <p>Review of facility policy and procedure titled, "Medication Storage in the Facility" (dated 4/2008) indicated medications are stored safely, securely, and properly, following manufacture's recommendations.</p> <p>Review of facility policy and procedure titled, "Medication Storage in the Facility" (dated 4/2008) indicated: "J. Medications requiring storage at 'room temperature' are kept at temperatures ranging from 15°C (59°F) to 30°C (86°F)."</p> <p>During an interview on 5/23/16 at 12:30 p.m., the</p>	A016	<p>Maintenance staff on 6/15/16 installed a good quality temperature gauge in the two medication rooms and a temperature log will be maintained of these medication rooms. The maintenance staff will check the temperature daily in the afternoon to ensure temperature is within range during the warm part of the day.</p> <p>IDT on 6/15/16 reviewed and updated Policy and Procedures for Storage of Medications to include maintaining the storage room not to go over 77 degrees Fahrenheit.</p> <p>2. The Patient care and policy committee will now meet on a quarterly basis to review and update out policies and procedures to reflect the most current practices and regulatory standards.</p> <p><u>Measures that will be implemented to monitor the continued effectiveness of the corrective action taken to ensure that this deficiency has been corrected and will not recur:</u></p> <p>1. The maintenance director will bring his log of daily temperature checks of the two medication rooms to the Quality Assurance and Assessment (QA&amp;A) meeting monthly. The QA&amp;A committee will review the log monthly and observe for any temperatures above 77 degrees. The committee will make recommendations as needed for further corrective actions if any temperatures are recorded on the log above 77 degrees Fahrenheit.</p>		6/29/16

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A 016	<p>Continued From page 5</p> <p>Administrator stated he was unaware the facility policy regarding medication room temperatures did not comply with manufacture's requirements.</p> <p>Review of online article by the Journal of Pharmaceutical &amp; Biopharmaceutical Contract Services titled, "Pharmaceutical Outsourcing," dated (9/25/13) indicated medications stored at incorrect temperatures could affect medication stability and quality. Temperature excursions occur during product's storage and transport from its manufacturing site to patient. (<a href="http://www.pharmoutsourcing.com/Featured-Articles/146648-Handling-Temperature-Excursions-and-the-Role-of-Stability-Data/">http://www.pharmoutsourcing.com/Featured-Articles/146648-Handling-Temperature-Excursions-and-the-Role-of-Stability-Data/</a>)</p> <p>2. Review of the Cubex ADC inventory list (dated 5/19/16) indicated it contained 10 types of controlled medication which included narcotic pain medications Oxycodone, Dilaudid, Morphine, Methadone, Oxycodone, Hydrocodone and anti-anxiety medications Ativan, Restoril, and Clonazepam). The list indicated the ADC contained 119 doses of these controlled medications.</p> <p>During an interview, on 5/18/16 at 2:50 p.m., the Director of Nursing (DON) stated the controlled medication in the ADC did not need to be counted by licensed staff because they were audited monthly by the pharmacist.</p> <p>During a interview, on 5/23/16 at 1:00 p.m., Pharmacist I stated the pharmacy tracked utilization of controlled medication in the ADC remotely (via computer access). She stated she inspected the ADC monthly and counted the controlled medication at that time.</p>	A 016	2. The Administrator will ensure that the Patient care and policy committee is scheduled and takes place on a quarterly basis.	6/29/16	



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A 016	Continued From page 6  Review of Cubex policy titled "Resolving Discrepancies," subtitled, "Automated Medication Storage Cabinet" (dated 12/31/13) revealed the discrepancies are researched and resolved in accordance to all state and federal regulations. The policy did not specify procedures how or when controlled medication would be monitored for accuracy and potential diversion.	A 016			

