

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 555235	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/03/2015
NAME OF PROVIDER OR SUPPLIER Seton Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 1900 Sullivan Ave, Daly City, CA 94015-2200 SAN MATEO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during a Complaint Investigation visit:</p> <p>CLASS AA CITATION -- PATIENT CARE 22-1827-0011305-S Complaint(s): CA00420906</p> <p>Representing the Department of Public Health: Surveyor ID # 21155, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Glossary of terms:</p> <p>ACLS: Advanced Cardiac Life Support or Advanced Cardiovascular Life Support; refers to a set of clinical interventions for the urgent treatment of cardiac arrest, stroke and other life-threatening medical emergencies, as well as the knowledge and skills to deploy those interventions.</p> <p>ADL's: Activities of Daily Living such as bathing, toileting, dressing and eating</p> <p>Anoxic: without oxygen</p> <p>Asystole: the heart stops beating and there is no electrical activity in the heart. As a result, the heart is at a standstill.</p> <p>Bipolar Disorder: formerly known as manic depression, is a mood disorder that causes radical emotional changes and mood swings, from manic,</p>			

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Judy Cook RN

Administrative Director

3/4/15

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 14

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

Judy Hren #21155 3/04/15

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	<p>restless highs to depressive, listless lows.</p> <p>Code Blue: a medical emergency in which a team of medical personnel work to revive an individual in cardiac arrest.</p> <p>Coroner: An official who inquires into the causes of accidental or sudden, unexpected deaths.</p> <p>CPR: Cardiopulmonary Resuscitation; Using rescue breathing and chest compressions to help a person whose breathing and heartbeat have stopped</p> <p>Diabetes: a metabolic disease in which the body's inability to produce any or enough insulin causes elevated levels of glucose in the blood.</p> <p>DNR: An abbreviation for Do Not Resuscitate - a physician's order not to initiate a Code Blue (see Code Blue)</p> <p>Dyspnea: difficult or labored breathing</p> <p>Fenestrated: A fenestrated trach tube is similar to other trach tubes but has one added feature. It has one or more holes in the outer cannula. The holes allow air to pass from the lungs up through the vocal cords and out through the mouth and nose. It allows the patient to breathe normally, speak using vocal cords, and cough out secretions(mucous) through the patient's mouth.</p> <p>Gross aspiration: breathing in a foreign object such as sucking in food into the airway</p>			

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	<p>Hypothermic Treatment: active treatment that tries to achieve and maintain specific body temperature in a person for a specific duration of time in an effort to improve health outcomes. This is done in an attempt to reduce the risk of tissue injury such as brain injury from lack of blood flow such as in a cardiac arrest.</p> <p>Hypoxic: a condition in which the body or a region of the body is deprived of adequate oxygen supply</p> <p>ICU: Intensive Care Unit</p> <p>IV: Intravenous</p> <p>Larynx: the voice box</p> <p>Laryngeal (pertaining to the larynx) Edema: A part of acute inflammation of the laryngeal mucosa due to infection, allergy or inhalation of irritant materials. It causes obstruction to air flow, stertor (heavy snoring or gasping), dyspnea (shortness of breath) and potentially asphyxia (suffocation).</p> <p>Morphine Drip: a drip is set up in a machine to deliver a specified amount over a designated time. Morphine is a pain relief medication.</p> <p>Passy-Muir Valve (PMV): a valve that attaches to the outside opening of the tracheostomy to help patients speak more normally. This one way valve attaches to the outside opening of the tracheostomy tube and allows air to pass into the tracheostomy, but not out through it. The valve opens when the patient breathes in. When the patient breathes out, the valve closes and air flows</p>			

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	<p>around the tracheostomy tube, up through the vocal cords allowing sounds to be made. The patient breathes out through the mouth and nose instead of the tracheostomy.</p> <p>PEG Tube: Percutaneous Endoscopic Gastrostomy is an endoscopic procedure in which a tube (PEG tube) is passed into a patient's stomach through the abdominal wall, most commonly to provide a means of feeding when oral intake is not adequate.</p> <p>Pneumonia: lung inflammation caused by bacterial or viral infection in which the air sacs fill with pus and may become solid.</p> <p>Pt: Patient</p> <p>Prognosis: the likely course of a disease or ailment</p> <p>Schizophrenia: a long term mental disorder involving breakdown in the relation between thought, emotion, and behavior, leading to faulty perception, inappropriate actions and feelings, withdrawal from reality and personal relationships into fantasy and delusion, and a sense of mental fragmentation. In general, a mentality characterized by inconsistent or contradictory elements.</p> <p>Tracheostomy (trach): a surgical procedure to create an opening through the neck into the trachea (windpipe). A tube is usually placed through this opening to provide an airway and to remove secretions from the lungs. This tube is called a tracheostomy tube or trach tube.</p>			

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	<p>Tracheostomy Cuff: The purpose of the cuff is to hold the tracheostomy tube in place and prevent the flow of air around the outside of the outer cannula. This allows for more effective ventilation of the patient and prevents the aspiration of liquids into the trachea.</p> <p>Ventilation: breathing Ventilator: a machine that supports breathing</p> <p>F328 483.25 (k) TREATMENT/CARE FOR SPECIAL NEEDS The facility must ensure that residents receive proper treatment and care for the following special services: Injections; Parenteral and enteral fluids; Colostomy, ureterostomy, or ileostomy care; Tracheostomy care; Tracheal suctioning; Respiratory care; Foot care; and Prostheses.</p> <p>This Requirement is not met as evidenced by: Based on interview and record review, the facility failed to ensure that Resident A received proper treatment and care for tracheostomy care when the Passy-Muir Valve was removed from the tracheostomy tube with the cuff still inflated on Resident-A. According to manufacturer's specifications and hospital policy, failure to deflate the tracheostomy cuff while the Passy-Muir Valve is attached would result in an airway obstruction and consequently the patient would be unable to</p>		<p>The Passy Muir Valve (PMV) was immediately removed & resuscitative efforts initiated. The resident was resuscitated & transferred to ICU.</p> <p>All residents with PMVs were assessed for proper PMV placement and cuff status; all were either not in place or were correctly in place. Plans of Care for all residents using PMV were reviewed and updated to include PMV. Education Records for all residents with PMV were reviewed and updated to include PMV education appropriate to resident and/or family.</p> <p>Director informally interviewed licensed nurses & asked them to describe the procedure they use to remove & replace the valve; all were able to verbalize the correct procedure.</p> <p>The PMV procedure was reviewed and revised to include the procedure for removal of the value and documentation of the removal. Only one PMV and one container will be kept at the bedside.</p> <p>Review of PMV procedure and return demonstration competency for PMV application & removal provided to all licensed nurses by RCP starting Thursday 12/4/14. With the exception of nurses who were on vacation or leaves of absence, all licensed nurses completed this competency with return demonstration.</p>	<p>12/9/14</p> <p>12/15/14</p>

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	<p>breathe. On 11/15/14, Resident-A was found by the staff in her room pulseless, and without respirations while her Passy-Muir Valve was still attached to her non-fenestrated tracheostomy tube which still had the cuff inflated. Resident-A died on 11/28/14 due to anoxic brain injury secondary to respiratory failure.</p> <p>Findings:</p> <p>Resident-A was admitted from a long term care facility to the hospital on 01/08/14 for management and treatment of pneumonia and respiratory failure. Additional diagnosis included diabetes, bipolar disorder and schizophrenia. Subsequently, Resident-A was placed on a ventilator(a machine that supports breathing) on 01/11/14, and on 01/25/14, the resident had a tracheostomy (a surgical procedure to create an opening through the neck into the trachea (windpipe). The resident was eventually weaned off the ventilator but because of profound swallowing dysfunction, the patient required a permanent tracheostomy. Resident-A did not have difficulties moving her upper extremities on her own but she was unable to walk, and was totally dependent on staff for her ADL's (Activities of Daily Living e.g. bathing, toileting, dressing etc.). Resident-A received all her nutritional support via a PEG tube (a feeding tube through the stomach). Resident-A knew to use the call light for her basic needs but had short term memory deficits and was moderately impaired with decision making She was able to verbally communicate via the Passy-Muir Valve(PMV) which she was able to use daily since 4/24/14. The</p>		<p>This competency will be completed annually with all licensed nurses. The non-vented residents with PMVs are the responsibility of nursing to insert & remove the PMV; they all have cuffless trachs so there is no risk of inflating the cuff when the valve is in place.</p> <p>Cuffless trachs have been ordered for unit stock supplies so that non-vented residents using PMV who are not at risk for aspiration will have cuffless trachs.</p> <p>All new admissions with PMVs or residents who are started on PMVs with cuffed trachs will be reviewed with the Medical Director to determine if a cuffless trach can be used to avoid the possibility that the valve can be in place and the cuff inflated.</p> <p>Cuffed trachs in the same size as the cuffless trachs will be immediately available at the bedside in case a cuffed trach is needed in an emergency.</p> <p>When the RN or LVN inserts or removes the PMV for non-vented residents who have cuffed trachs, there will be a double check and documented verification by an RCP that placement/removal was correct, cuff pressure is correct and resident is not in respiratory distress.</p>	

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	<p>physician order dated 4/24/14 read, " Pt to wear PMV daily (with) nursing from (7 AM to 11 PM) as tolerated". The resident was stable at her baseline state until 11/15/14.</p> <p>During an interview on 12/02/14 9:45 AM, Staff-1 stated she completed Resident-A's evening care which took about 15 minutes, and left her bedside approximately 8:45 PM on 11/15/14. Staff-1 stated she was confident that she removed Resident-A's Passy-Muir Valve and reinflated the tracheostomy cuff after the evening care. Staff-1 stated she stored the PMV in the resident's night stand drawer which was across the foot of Resident A's bed where it was unreachable by the resident. Staff-1 stated Resident-A was alert and was not in distress when she left the resident's room.</p> <p>During an interview on 12/02/14 at 1:03 PM, Staff-2 who assisted Staff-1 with the Resident-A's evening care on 11/15/14 stated although she did not witness Staff-1's actions, she remembered Staff-1 verbally informing her that she stored the PMV in the resident's night stand and that she reinflated the trach cuff before they left Resident-A's room.</p> <p>Record review on 12/02/14 of the facility's documented staff interviews showed that on 11/15/14 at 8:52 PM, the resident was found unresponsive in her bed. But the Code Blue was not called to the hospital operator until 9:04 PM. During an interview on 12/02/14 starting 9:30 AM, Administrator-1 stated the Code Blue was delayed because the resident's code status was unclear. The hospital policy for patients to wear the Do Not</p>		<p>Documentation will be monitored monthly by the Director for six months to ensure that the insertion & removal of the PMV for non-vented residents who have cuffed trachs is documented by nursing and verified by RCP. On-going monitoring will occur quarterly thereafter for six months. The Director will incorporate the monitoring in the performance improvement plan and report findings to the LTC PI Committee at every meeting. The Committee meets six times a year.</p>	

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	<p>Resuscitate(DNR) purple wrist band was not practiced on the unit hence contributing to the delayed resuscitation efforts of Resident-A.</p> <p>During an interview on 12/02/14 starting 10:17 AM, Staff-3 stated on the evening of 11/15/14, she was asked by another employee (Staff-4) to check on Resident-A who was "not breathing, pulseless & gray colored". Then, Staff-1 entered the room and asked why the PMV was on the resident. At that moment, Staff-3 noticed the trach cuff was inflated so she deflated the cuff. Record review on 12/02/14 of the facility's documented staff interviews showed that Staff-3 stated the following: "She was positive cuff was inflated stated, 'That's my job' ", and, " Asked why she did not start CPR right away since there was no purple DNR band. She stated that on this floor residents rarely have DNR bands on". Additionally, Staff-3 indicated that, "There were 3 PMV containers in her drawer, but only 2 PMV's were found, (she) wondered if resident had one hidden which she could have put in herself".</p> <p>During the interview on 12/02/14 at 9:45 AM, Staff-1 stated that she noticed the PMV was not properly placed in the trach when the Resident-A was found unresponsive, and the drawer of the night stand where the PMV was stored was open and appeared sloppy which is not how she left it after she was done with the evening care. Staff-1 stated she remembered only seeing two PMV containers after she stored the valve.</p> <p>During an interview on 12/02/14 at 10:47 AM, Staff-4 went to Resident A-'s roommate on the</p>			

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	<p>evening of 11/15/14. Staff-4 described Resident-A as pale and he tried to wake her up. Staff-4 stated Resident-A was panting (short of breath). Staff-4 saw Staff-3 and told her to check the patient.</p> <p>During the interview on 12/02/14 at 9:30 AM, Administrator-1 stated that their internal investigation did not discover who could have placed the Passy-Muir Valve without deflating the trach cuff on Resident-A. Administrator-1 stated there was no nursing care plan and patient education regarding the Passy-Muir Valve and acknowledged there should have been a care plan. As a result, there was no documentation by the clinicians caring for Resident-A that demonstrated consistent and standardized care was delivered to ensure an optimum level of care was given toward the care of a patient with a Passy-Muir Valve. The American Nurses Association (2015), a professional organization representing registered nurses and is involved in establishing standards of nursing practice, states, " Based on the assesment and diagnosis, the nurse sets measurable and achievable short and long range goals for the patient..., Assessment data, diagnosis, and goals are written in the patient's care plan so that nurses as well as other health professionals caring for the patient have access to it. Nursing care is implemented according to the care plan, so continuity of care for the patient during hospitalization and in preparation for discharge needs to be assured. Care is documented in the patient's record". Without a specific document delineating the plan of care, important issues may be neglected.</p>			

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	<p>During the same interview on 12/02/14 at 9:30 AM, Administrator-1 stated the policy and procedure for the Passy-Muir Speaking Valve was updated since the incident occured with Resident-A. Record review on 12/02/14 showed the updated policy revised 11/14 included the following new procedures: "B. Removing Passy-Muir Valve: 1. Clear both tracheal and oral secretions by having resident cough or by suctioning, if necessary, 2. Twist valve counterclockwise and remove, 3. Inflate cuff to prevent aspiration, 4. Wash valve, dry and store in Passy-Muir Valve container. Documentation: 1. The speaking valve will be care planned as method of communication, 2. Duration, frequency and tolerance of the Passy-Muir speaking valve when used by the resident will be documented on the resident's treatment sheet and electronic medical record with each appication and removal. Once resident is comfortable with use of Passy-Muir, use of Passy-Muir will be documented on treatment sheet with initials of licensure attending resident during the shift..."</p> <p>During an interview on 12/02/14 at 10:58 AM, Physician-1 stated that he instructed Resident-A regarding the PMV when she first got it but he wasn't sure if the staff performed education with Resident-A on her PMV.</p> <p>During an interview on 12/02/14 at 11:40 AM, Staff-5 stated there is no formal check-list for training with patients or family regarding Passy-Muir Valves. During the same interview, when asked if residents get education when they</p>			

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	<p>have a PMV, Staff-6 stated, " Usually the speech therapist initially educates the resident".</p> <p>The History and Physical Report by Physician-2 dated 11/15/14 indicated, "On the evening of (11/15/14), the circumstances surrounding the event are somewhat unclear, however, apparently, the patient had respiratory arrest on the ward secondary to complications of retract on trach without deflation of the cuff. The patient subsequently then developed a cardiac arrest asystole. The patient was resuscitated per ACLS protocol for approximately 25 minutes and subsequently, a sustainable pulsatile and circulating rhythm was returned..., Diagnostic Impression: ... 2. Primary respiratory arrest secondary to BiCAP placement without cuff deflation...".</p> <p>Record review on 12/02/14 showed Physician-3 dictated the following on 11/21/14: " The patient was apparently down for at least 20 to 25 minutes. She received a CPR as per ACLS protocol with her return of spontaneous circulation. She was subsequently transferred to the ICU, where she underwent hypothermic treatment for 24 hours. However, despite return of circulation and hypothermia treatment, she sustained significant hypoxic and brain damage and did not regain her prior cognitive function. After an extensive discussion with the family about her prognosis, decision was made to withdraw care and stop supportive treatment on the 20th. Subsequently, she was taken off the ventilator. All diagnostic lab draws and IV medications were stopped. She was</p>			

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	<p>put on morphine drip for pain and dyspnea...". Resident-A was transferred back to the original unit she came from.</p> <p>Record review on 12/02/14 showed Physician-1 dictated in his discharge summary dated 11/28/14 the following: "Diagnosis: Persistent Vegetative State ...Family had requested for the ventilator to be discontinued in the ICU and the patient survived. She was transferred (back to the unit she came from) for ongoing management. The family did not want any blood tests or any aggressive interventions performed. The patient was maintained comfortably. She expired on the afternoon of 11/28/2014. The cause of death is anoxic brain injury secondary to respiratory failure". During the interview on 12/02/14 at 10:58 AM, Physician-1 stated the coroner declined the case on 11/28/14 regarding Resident-A's death so an investigation as to the manner or cause of death or autopsy was not performed.</p> <p>The facility's policy and procedure titled, "Passy-Muir Speaking Valve", date revised 9/14, indicated the following: " ...Scope: Respiratory Care Practitioners, registered nurses and licenses vocational nurses , Hazard/Complications/Precautions, 1. Do not use with inflated cuff...". On an interview on 12/02/14 at 9:45 AM, Administrator-1 stated the registered nurses, licensed vocational nurses and clinical nursing assistants were retrained about the facility policy and procedures regarding the Passy-Muir Valve.</p>			

Event ID:TXLD11

3/4/2015

10:16:22AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 555235	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/03/2015
NAME OF PROVIDER OR SUPPLIER Seton Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 1900 Sullivan Ave, Daly City, CA 94015-2200 SAN MATEO COUNTY		
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	<p>On an interview on 12/02/14 at 11:40 AM, Staff-7 stated the licensed practitioners on the unit Resident-A resided are required to do a one time, four hour respiratory orientation with a respiratory therapist that includes a checklist titled, "Passy-Muir Tracheostomy & Ventilator Speaking Valve Competency Checklist". This checklist has the clinician return demonstrate skills on how to "deflate cuff on tracheostomy tube slowly & completely...". An inflated trach cuff used together with the PMV would cause an airway obstruction and the patient would be unable to breathe. The Director of Staff Development provided documentation that every licensed staff on the unit successfully passed and completed this orientation and competency spanning from 5/30/1995 to 8/11/2014.</p> <p>According to the Passy-Muir Valve manufacturer's product description titled, "Passy-Muir Tracheostomy and Ventilator Speaking Valve Resource Guide" developed by Passy-Muir Inc. March 2003: "Contraindications for Use of the Passy-Muir Speaking Valve, A. Inflated Tracheostomy Tube Cuff: Controlling ventilation and gross aspiration are the two main issues that influence the decision to utilize a cuffed tracheostomy tube. If, for either of these reasons, the cuff cannot be deflated, then the PMV cannot be used as the cuff would cause an obstruction to exhaled air flow and the patient would be unable to exhale/breath..., If the patient has a cuffed tracheostomy tube, it is imperative that the cuff be fully deflated prior to PMV placement...".</p>			

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	<p>Record review showed the last tracheostomy tube change on Resident-A was on 10/31/14 at 5:04 PM. The tube was a Portex 8.0mm cuffed trach. Administrator-1 stated on a fax report dated 01/07/15 at 4:22 PM, Portex tubes are not fenestrated. With the PMV attached to the trach with a fully inflated cuff, Resident-A would have been unable to breathe.</p> <p>The hospital failed to follow their policy and procedure, and the manufacturer's recommendations for a Passy-Muir Valve that was left on a non-fenestrated trach with an inflated cuff on Resident-A. This failure presented either imminent danger that death or serious harm would result or a substantial probability that death or serious physical harm would result and was a direct proximate cause of death of Resident A.</p>			

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