

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 555236	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/05/2011
NAME OF PROVIDER OR SUPPLIER SETON MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 1900 SULLIVAN AVENUE, DALY CITY, CA 94015 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 22-2103-0008904-F Complaint(s): CA00274771</p> <p>Representing the Department of Public Health: Surveyor ID # 25732, 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>F 328 483.25(k) TREATMENT/CARE FOR SPECIAL NEEDS</p> <p>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 regulation was not met as evidenced by:</p> <p>Based on interview and record review the facility failed to ensure one patient who had a tracheostomy (Resident A) received proper respiratory care when:</p>		<p>1. Review competencies on the SubAcute Unit, specifically tracheostomy and T-piece care; enhance competencies and educate as needed.</p> <p>a. This was completed during the week of July 11, 2011 with further inservicing in August by involved staff i. Responsible Person: Manager and Director, Staff Development (DSD)</p> <p>b. All staff was re-educated on the equipment during the week of July 11, 2011 i. Responsible Person: DSD</p> <p>c. The nurse involved in the case was placed on extended orientation with ample opportunity to review this competency with both Respiratory Therapy (RT) and Nursing i. Responsible Person: SubAcute Manager (BF) and DSD</p> <p>d. Ongoing monitoring: Competencies are reviewed annually with RT, through face-to-face training and observations with return demonstrations</p> <p>2. Review orientation to equipment with hands on demonstration and multiple return demonstrations</p> <p>a. This was completed during the week of July 11, 2011 with further inservicing in August by involved staff i. Responsible Person: DSD and RT</p> <p>b. The nurse involved in the case was placed on extended orientation with ample opportunity to review this competency with both RT and Nursing i. Responsible Person: SubAcute Manager (BF) and DSD</p> <p>c. Ongoing monitoring: Orientation to equipment with hands on demonstration has been integrated into the annual competency review with RT. As above, this is done through face-to-face training and observations with return demonstrations</p>	

Event ID: S8S11

1/11/2012

2:43:53PM

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

TITLE

(X6) DATE

Dennis Kent

Director Quality

11/2/12

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I accept this POC 1/12/12 Stuppel HFEN

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	<p>Continued From page 2</p> <p>her airway. She was totally dependent on staff for her activities of daily living.</p> <p>According to the annual Minimum Data Set (MDS) dated 11/15/10, and the latest quarterly MDS dated 5/15/11, under Special Treatments, Procedures and Programs, the following Respiratory Treatments were performed on the patient: oxygen therapy, suctioning and tracheostomy care.</p> <p>Record review of a Nursing Care Plan, dated 11/12/10 and updated on 1/19/11, indicated: "Problems...Impaired airway clearance related to tracheostomy and respiratory failure. Goal: Resident's airway will remain patent X 90 days- as evidenced by a SaO2 above 93%" (oxygen saturation-a measurement that indicates adequate oxygen is being taken into the body for life, measured by a bedside device).</p> <p>According to the Nursing Care Plan updated on 4/19/11, it indicated under Needs/ Problems section that Patient A had potential problem for aspiration secondary to presence of tracheostomy and tube feeding. The Action Plan was to: Auscultate lungs q (every) shift and prn (whenever necessary), Report changes in lung sounds to MD, ..."</p> <p>Record review of Treatments Sheet for 6/1/11-6/24/11 indicated a treatment order dated 11/12/09 to "suction q (every) 2 H (hours) and prn. It also indicated an order to "Keep SaO2 at 93% or greater at all times." and "Trach. care Q (every) shift and</p>		<p>5. Review process where changes of tubing are assigned to nurses not directly caring for the resident.</p> <p>a. This was completed during the week of July 11, 2011. This process was revised so that the nurse caring for the patients is responsible for the tubing change.</p> <p>i. Responsible person: Subacute Manager (BF)</p> <p>ii. Ongoing monitoring: The SubAcute Manager evaluates the day shift assignment (the shift when tubing is changed) daily to ensure that this new practice is being followed.</p> <p>6. Review process with staff regarding documentation of treatments (which would include auscultation of lungs and documentation and Oxygen Saturation and documentation) as outlined in the Nursing Care Plan and Treatment Sheet</p> <p>a. This was completed during the week of July 11, 2011</p> <p>i. Responsible person: DSD</p> <p>ii. Ongoing monitoring: As a part of the Performance Improvement activities for the SubAcute Unit, a random sample of patients will be chosen each month to ensure that the Treatment Record and the Nursing Care Plan coincide and the documentation is complete. In addition, this documentation will be reviewed during the regularly scheduled Interdisciplinary Team Meeting.</p> <p>7. This plan of correction applies to all residents on the SubAcute as they are all with tracheostomy tubes</p>		

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1/11/2012

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Alvise Kent

TITLE

Director, Quality

(X6) DATE

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	<p>Continued From page 3 prn (when necessary)..."</p> <p>Record review of Resident A's Long Term Clinical Care Flowsheet for 6/21/11, 6/22/11, 6/23/11, and 6/24/11 indicated that the box for recording the SaO2 was left blank. There was no documented evidence that nursing staff had checked Patient A's SaO2.</p> <p>In an interview, on 10/6/11 at 11 A.M., the Risk Manager 1 (RM 1) and the Chief of Respiratory Therapy acknowledged that the nursing staff did not routinely measure Patient A's SaO2 on 6/22/11, 6/23/11, and 6/24/11 before this reported incident.</p> <p>Record review of a Physician Progress Note for Resident A, dated 6/16/11 indicated, "Subjective: The patient does not respond to stimuli. Objective: Vital Signs...blood pressure 116/68...Chest: No wheezing... Assessment: Respiratory failure, tracheostomy, gastrostomy, no ventilator dependency..."</p> <p>Record review of Progress Notes dated 6/24/11 at 3:23 P.M., indicated: "RN 1 called to inform that patient was found pale, non-responsive, Vital Signs (blood pressure and pulse) could not be appreciated, no spontaneous breathing. Rapid Response team called, but canceled due to patient's DNR (do not resuscitate)."</p> <p>Record review of a Physician Progress Notes, dated [redacted]/11 at 6:25 P.M., indicated: "Called by nursing staff to pronounce patient who they say died at 3:15 P.M.. Patient is in fact dead with</p>		<p>8. The Policy/Procedure describing the operation of the involved suction catheter "Inline Suction Catheter Assembly" (attached) has been developed and approved effective December 2011. This policy/procedure reflects the current existing process and the staff were familiarized with it during December staff meeting. In addition, it has been added to the annual competency training.</p>	

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	<p>Continued From page 4</p> <p>dilated pupils no respiratory effort and is pulseless. A T-piece is attached to a tracheostomy. The expirator port is occluded with a plastic cover."</p> <p>In an interview, on 7/15/11 at 11 A.M. the facility's RM 1 provided a summary of the reported adverse event as follows: "On [REDACTED]/11 at 3:15 P.M. LVN 1 (Licensed Vocational Nurse) went into Patient A's room to change the T-piece suction set up attached to the tracheostomy. The T-piece is a closed device that is attached to the tracheostomy for suctioning (method of removing secretions that accumulate in the lungs and wind pipe). Patient A was not on a ventilator (breathing machine) but was breathing humidified air and oxygen through this T-piece on her own. When the T-piece comes in the package for changing it comes with a cap on the expiration port. The cap must be removed prior to use when the patient is breathing on her own. Essentially, LVN 1 did everything right except she left the cap on. She said she took the cap off. When another nurse (LVN 2) came in to check on Patient A, she saw the cap was on the T-piece expiration port and the patient was not breathing on her own. LVN 2 immediately removed the cap and began bagging (device used to provide rescue breathing) the patient. Patient A never started breathing on her own again...since she was DNR, she was pronounced dead."</p> <p>In an interview on 7/15/11 at 11:30 A.M., Respiratory Therapist 1 (RT 1) (a respiratory therapist helps evaluate, treat and assist the health care team with patients with respiratory disease) who assisted LVN 2 in the above described incident</p>			

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	<p>Continued From page 5</p> <p>was asked if Patient A was a spontaneously breathing patient. RT-1 said, "Patient A was not on a ventilator. She was breathing on her own. The white cap should have been off of the T-Piece. There should have been a little plastic tube connected to the T-piece so the patient could exhale."</p> <p>In an interview on 7/15/11 at 12:27 P.M., LVN 1 was asked about changing the T-piece on Patient A. LVN 1 said, "I remember coming in to Patient A's room with LVN 3 at about ten minutes to three to change the T-piece. The T-piece was used to suction the patient through a trach (tracheostomy), we change it every three days. Since this patient was on oxygen and breathing on her own we took the white cap off. I remember changing the T-piece. Everything was all right with the patient when I left the room." LVN 1 was then asked if she remembered who took the white cap off of the T-piece expiration port. LVN 1 said, "Honestly, I can't remember."</p> <p>In an interview on 7/15/11 at 1:15 P.M., LVN 2 who discovered Patient A was not breathing on [REDACTED] 11, was asked to describe what happened. LVN 2 said, "It was a [REDACTED] at about five minutes to 3 P.M., I was going on my rounds and checking on Patient A in her room. Looking at her I did not think she was breathing. I shook her and I saw right away that the T-piece had a cap on it and she was not breathing so I called for help, took the T-piece completely off and started bagging her."</p> <p>The surveyor asked LVN 2: "When you took the</p>				

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	<p>Continued From page 6</p> <p>T-piece off the tracheostomy of Resident A, was the white cap on or off ?" LVN 2 said, "That cap was on, it should have been off." LVN 2 was asked what would happen to the patient if the cap was left on. LVN 2 explained, "If the white cap was left on, the patient cannot exhale and breathe on her own."</p> <p>Review of Resident A's San Mateo County Coroner's Office combined Autopsy Report and Pathology Report dated 8/31/11, indicated: "Conclusion: The cause of death listed was asphyxiation due to obstruction of tracheostomy tube. Patient A was in a persistent vegetative state after suffering a cerebral vascular accident in 2009. Patient A was a patient at the hospital. On [REDACTED] 2011 at approximately [REDACTED] hours [REDACTED] P.M.), the subject's tracheostomy tube was replaced, but the cap was not properly removed preventing oxygen to the subject. Based on information obtained in the Coroner's Investigation Report and Autopsy Report, I have determined that the manner of death to be an accident."</p> <p>Review of the manufacturer's directions for use of the Kimberly-Clark KimVent Turbo-Cleaning Closed Suction System dated 2007, indicated: "Warning: Cap on KimVent T-Piece prevents continuous flow therapy (oxygen is administered through a tube to a breathing patient with a tracheostomy). Remove cap before starting continuous flow therapy. Failure to remove cap prior to continuous flow therapy may result in serious injury or death."</p> <p>Review of the LVN 1's competency Action Plan, dated 5/2/11, indicated : "In-line Suction</p>				

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	<p>Continued From page 7</p> <p>Catheter/White Cap Set-up... Ensure all licensed Respiratory Care Practitioners and licensed Nursing personnel on the Subacute Unit clearly understand the two different set -ups, for the in-line suction catheter when used with a ventilator and when used on a spontaneously breathing patient i.e.,without a ventilator. Additionally, ensure the aforementioned staff understands why the white cap is not to be placed on the in-line suction catheter when the patient is not on the the ventilator."</p> <p>In an interview, on 10/5/11 at 11:30 AM, the Chief Respiratory Therapist was asked if there was a facility policy and procedure that described the training and the operation of the Kim Vent T-piece device. The Chief Respiratory Therapist said, " No, I checked with Nursing. The only policy is the Action Plan competency check list that Respiratory Care uses to train the nurses who use the KimVent."</p> <p>In a phone interview, on 9/15/11, the Kimberly Clark manufacturer's clinical care representative was asked to explain why the white cap needed to be removed from the T-piece part of the Kimberly-Clark KimVent Turbo-Cleaning Closed Suction System when it was used on a spontaneously breathing patient. The clinical care representative said, "When the patient is breathing on her own through the T-piece, if the white cap is not off the patient cannot exhale. It is like suffocating the patient."</p> <p>In a phone interview, on 9/27/11 at 2:44 P.M., LVN</p>				

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	<p>Continued From page 8</p> <p>3 was asked what she remembered about changing Patient A's T-Piece on 4/11. LVN 3 said, "LVN 1 asked me to help her change the tubing. LVN 1 handled the T-Piece. I was in the back of the bed changing the oxygen tubing and water bottle. LVN 1 was in front of Patient A. I handed her the tubing and she connected to the T-Piece. Then she connected it to Patient A. I then left the room. LVN 3 was then asked if she had removed the white cap from the T-Piece. LVN 3 said, "No." LVN 3 was then asked if LVN 1 had removed the white cap from the T-Piece. LVN 3 said, "I don't remember. Patient A was breathing on her own when I left the room."</p> <p>The facility failed to ensure that Patient A who had a tracheostomy, received proper respiratory care when:</p> <ol style="list-style-type: none"> 1. There was no documented evidence of Patient A's oxygen saturation (SaO2) levels on 6/22, 6/23, and 6/24/11 to ensure it was maintained at or greater than 93%. 2. The facility failed to maintain the resident's airway patent when a staff (LVN 1) did not remove the cap from the expiratory port of a T-piece which is one part of a medical device known as the KimVent Turbo-Cleaning Closed Suction System attached to Patient A's tracheostomy tube. The deficient practice caused the death of Patient A on 4/11 due to asphyxiation as a result of obstruction of the tracheostomy tube. The facility's failure presented an imminent danger to the patient and was a direct proximate cause of death of the 			

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