

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>CA230000010</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>C</b> <b>10/06/2016</b>
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

**MERCY MEDICAL CENTER REDDING**

**2175 ROSALINE AVE, CLAIRMONT HGTS  
REDDING, CA 96001**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 001	Informed Adverse Event Notification  Health and Safety Code Section 1279.1 (c), "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."  The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.	A 001		
E 000	Initial Comments  The following reflects the findings of the California Department of Public Health during the investigation of one entity reported incident.  Entity reported incident: 495562  This inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.  Representing the Department: 22705, Health Facilities Evaluator Nurse.  Deficiencies were written for entity reported incident 495562 at E292 and E294 .	E 000		
E 292	T22 DIV5 CH1 ART3-70215(a)(2) Planning and Implementing Patient Care  (a) A registered nurse shall directly provide: (2) The planning, supervision, implementation, and evaluation of the nursing care provided to each patient. The implementation of nursing care may be delegated by the registered nurse	E 292		

Licensing and Certification Division

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

TITLE

(X6) DATE

STATE FORM

6899

R8ZM11

If continuation sheet 1 of 8

*[Handwritten Signature]*

*PRESIDENT/CEO*

*5/3/19*

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E 292	Continued From page 1  responsible for the patient to other licensed nursing staff, or may be assigned to unlicensed staff, subject to any limitations of their licensure, certification, level of validated competency, and/or regulation.  This Statute is not met as evidenced by:	E 292		
E 294	T22 DIV5 CH1 ART3-70215(b) Planning and Implementing Patient Care  (b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission.  This Statute is not met as evidenced by: Based on interview and record review, the facility failed to implement nursing care per physician's order and advocate for the patient when an error was suspected, when Patient 1 underwent Continuous Renal Replacement Therapy (CRRT, a process in which blood passes through a membrane and wastes are removed. Fluid removal is achieved at an established hourly rate and on a continuous basis).  1. When CRRT was initiated, the fluid removal rate, rather than being set according to the physician's order, was set at 10 times the amount. Although the rate was checked by both the Dialysis and Intensive Care Unit Registered Nurses (RN), neither recognized the rate was not set according to the physician's orders. 2. CRRT was allowed to continue at the incorrect rate, without being recognized and fully corrected	E 294		

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E 294	<p>Continued From page 2</p> <p>for over eight hours. This resulted in hypotension (low blood pressure) and dehydration (when a person uses or loses more fluids than taken in so the body does not have enough water and other fluids to carry out its normal functions) which contributed to Patient 1's death.</p> <p>Findings:</p> <p>1. CRRT is a process in which blood passes through a membrane (hemofilter or dialyzer) and wastes are removed. Fluid removal is achieved by ultrafiltration at an established hourly rate and on a continuous basis. Because fluid removal with CRRT is much slower than with intermittent dialysis, CRRT is an ideal therapy for critically ill patients in unstable conditions. Removing fluid more slowly and in smaller volumes in hours or days may provide enhanced hemodynamic stability. The CRRT system infuses and removes fluid after the fluid balance is calculated and the desired volumes are input to the system. The system monitors the volume of fluids infused and the volume of fluid removed on an ongoing basis. (Critical Care Nurse April 2007 vol. 27)</p> <p>The hospital policy relating to care of patients on CRRT, dated 8/2012, referred to the Manufacturer's (Mfr) Manual. The Mfr's manual indicated hourly checks on the patient to include the Ultrafiltration Rate (UFR, the rate at which fluid is removed from the patient's body during dialysis) from the last hour from the history screen. Fluid volume settings for liters per hour were indicated as 0.00 and for milliliters (ml) per hour were indicated as 000.</p> <p>Patient 1's record was reviewed. Patient 1 was admitted on 6/22/16 with diagnoses that included</p>	E 294		

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E 294	<p>Continued From page 3</p> <p>congestive heart failure, valvular heart disease, and lung disease. She underwent open heart surgery including heart valve surgery on 6/27/16 and was placed in the Intensive Care Unit (ICU). Patient 1 later developed respiratory failure and kidney failure. On 7/9/16, there was a physician's order to start CRRT with a Net UFR of -25 per hour.</p> <p>During an interview on 8/6/16 at 11:30 am, Dialysis Registered Nurse (DRN A) explained CRRT was not the typical intermittent dialysis but rather 24 hours/day dialysis that was performed on hemodynamically unstable patients. DRN A stated hypotension (low blood pressure) was a side effect of CRRT. DRN A further explained that, once the physician wrote an order for CRRT for Patient 1, DRN A was called to come to the facility and set up the dialysis machine. She stated she arrived at the facility on 7/9/16 around 2 am, completed an assessment of Patient 1 and reviewed the physician's order. DRN A stated the physician wanted 25 ml of fluid per hour taken off and Patient 1 was receiving 76 ml/hr of fluid so the dialysis machine should be set at 100 ml/hr (100-76=24). After the machine was set up, she and the ICU RN (IRN) B reviewed the machine settings, then she left the facility. DRN A stated it was her responsibility to set up the machine in accordance with the physician's orders. DRN A stated she found out later that afternoon the machine had been set in liters and not milliliters (ml). DRN A confirmed that was her error.</p> <p>DRN A stated responsibility for continuing CRRT was the responsibility of the ICU RNs and hourly checks should be done by the ICU nurses for patients receiving CRRT.</p> <p>During an interview on 8/16/16 at 12:20 pm, DRN</p>	E 294		

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E 294	<p>Continued From page 4</p> <p>E (Dialysis Administrator) stated the dialysis machine's manufacturer (Mfr) allows two settings, liters and ml. DRN E provided a copy of how the machine settings look when set at ml and liters: 100 (100 milliliters per hour) and 1.00 (liters per hour).</p> <p>During an interview on 8/8/16 at 10:45 am, DRN F (Dialysis Administrator) stated the machine that had been used for Patient 1's CRRT had preventative maintenance performed prior to being used for Patient 1. The Biomedical representative who performed the maintenance set the machine's rate to liters.</p> <p>2. During an interview on 8/8/16 at 7:30 am, IRN B stated DRN A had set up the machine and then they both agreed on the numbers as to how much fluid was going to be removed each hour. After the set up was completed DRN A left and IRN B assumed care of the patient. IRN B stated the ICU RNs would call the Dialysis RN if there were any problems. IRN B stated if a CCRT patient's Blood Pressure (BP) started dropping, "you would check to see how much fluid was being removed." IRN B stated "we" checked to see how much fluid was removed each hour and the CRRT patient was 1:1 nurse patient ratio. IRN B stated both he and DRN A thought the dialysis machine was set to remove fluid at 100 ml/hr. After a review of his notes he stated he recorded 30 ml as being removed at 5 am and 94 ml at 6 am. IRN B gave bedside report to the day shift RN. When he came back on duty for the night shift he was told by IRN D, there had been a problem with the volume taken off and there had been a decimal point on the dialysis machine which had indicated liters of fluid were removed and not milliliters.</p>	E 294		



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E 294	<p>Continued From page 5</p> <p>During an interview on 8/18/16 at 8 am, IRN C stated when he came on duty on 7/9/16, he received bedside report about Patient 1 from IRN B. IRN C stated he saw the decimal point on the machine and confirmed with IRN B that 100 ml per hour of fluid was being taken off. He stated although he noticed the decimal point on the machine, he didn't want to be disrespectful and question IRN B, who had more experience taking care of patients on CRRT. IRN C stated he mentioned Patient 1's BP, which was on the low side, to IRN B who said, we've been struggling with her BP.</p> <p>After review of Patient 1's record, IRN C confirmed Patient 1's BP was 93/55 at 6 am, 88/53 at 7 am, and remained in the 80's until 10 am, at which time it had dropped to 77/48, then 76/50 at 2 pm, 66/40 at 5:45 pm, and 56/29 at 6 pm. IRN C discussed Patient 1 with IRN D (ICU Supervisor) shortly after 10 am. IRN C stated he didn't think there was a problem with the machine until around 2 pm when he returned from lunch and was told Patient 1 had 10 times the amount of fluid removed than she should have.</p> <p>During a concurrent interview and record review on 8/18/16 at 8 am, IRN C reviewed his charting of the amounts taken off. He had originally entered 93 ml at 7 am then amended his charting to reflect the correct amount of 930. On the top of the machine, .93 was showing but he thought that meant 93 ml and not 930 ml. Other charting changed from: 95 ml to 950 ml at 8 am and 9 am, 42 ml to 420 ml at 10 am, 51 ml to 510 ml at 11 am, 62 ml to 620 ml at 12 pm, and 36 ml to 360 ml at 1 pm.</p> <p>During an interview on 8/16/16 at 2 pm, IRN D, stated he discussed Patient 1, who had</p>	E 294		

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E 294	<p>Continued From page 6</p> <p>hypotension, with her physician and IRN C shortly after 10 am. Various changes were then made to the dialysis machine settings to decrease the amount of fluid taken off although IRN D stated he could not set it at the number he wanted. IRN D stated the machine had a history that contains the amount of fluid removed and when he reviewed it, around 11 am, he saw that it was about 10 times the amount that should have been removed.</p> <p>In a letter to the facility, dated 9/2/16, the Mfr explained the results of the evaluation done on the machine used for Patient 1's dialysis.</p> <p>Evaluations were done for two cycles of dialysis, the first one which started on 7/9/16 at 4:39 am and stopped at 4:40 pm. The UFR in use started at 1 liter per hour for 5 hours 31 minutes, was adjusted down to 0.3 liters (300 ml) for 1 hour, adjusted to .64 liters per hour for 1 hour 47 minutes. One final adjustment was made where the UFR was increased to 1.72 liters per hour for five minutes. The total UF volume removed from the patient was 7 liters.</p> <p>The second cycle which started on 7/9/16 at 8:49 pm and stopped at 4:55 pm on 7/10/16 had an UF of 730 milliliters.</p> <p>Mfr's conclusion when comparing the two files analyzed for this event was the UFR for the first cycle was set to a much higher rate, approximately 10 times higher, then the UFR for the second cycle. There was no indication of a malfunction or product deficiency.</p> <p>The facility's failure to implement nursing care per physician's order and/or advocate for the patient, resulted in a situation in which the licensee's non-compliance with one or more licensure</p>	E 294		

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E 294	Continued From page 7  requirement (separately, jointly, or in any combination), caused or was likely to cause serious injury or death.	E 294		



## **CORRECTIVE ACTION PLAN**

**TAG # E292, E294**

### **A. Immediate Actions**

1. The Director ICU immediately removed the involved device from service and replaced it with another device from inventory that had been safety checked to prevent reoccurrence.

**7/12/2016**

2. The Director ICU coached the Registered Nurse (RN) involved in the care of the patient to speak-up regarding patient care concerns to decrease risk and ensure patient safety and quality care. Also, the dialysis device filtration setting unit-of-measure issue was disseminated to other ICU RN users via work shift huddles as well as the learning being shared with the dialysis RNs.

**7/12/2016**

3. The Patient Safety Officer met with the dialysis provider's Acute Services Facility Administrator to ensure that the dialysis device filtration setting unit-of-measurement is set to milliliters during the periodic preventive maintenance process prior to return to the facility. The sequestered device was returned to the manufacturer for evaluation.

**July-2016**

4. The Director Perioperative Services met with the dialysis provider's Acute Services Facility Administrator to establish the co-signature validation between the primary ICU RN and the dialysis RN of the initial device settings for the continuous renal replacement therapy/continuous veno-veno hemofiltration (CRRT/CVVH) procedure. ICU staff was educated via departmental huddles as to the expectations for double-checking physician therapy orders and the fluid removal setting in milliliters as evidenced by dual signatures.

**7/19/2016**

### **B/C. Deficient Practice/Corrective Action/Measures & Systemic Changes**

1. The Director Intensive Care, in collaboration with the device vendor's clinical educator and the ICU Clinical Educator, provided mandatory in-service training for ICU RN personnel. Both super-user and end-user training sessions for pertinent RNs were completed. Basic training included CRRT procedural phases: Initial/Subsequent Setup, Start of Treatment, and After Initiation of Treatment. The ICU Clinical Educator provides, on an ongoing basis, mandatory initial and annual refresher CRRT training.

**10/20/2016, 10/24-28/2016**

2. The Director Perioperative Services/Dialysis, in collaboration with the Director ICU, ICU Clinical Educator, and Patient Safety Officer, developed a new policy document for Continuous Renal Replacement Therapy (CRRT) that provides for the safe care of the patient undergoing CRRT implemented as ordered by a physician in collaboration

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Redding, CA 96001  
CA230000010

with the dialysis nurse. To protect the patient's health and safety, the expanded policy includes expectations for (1) nursing roles of the dialysis RN and CRRT-trained RN (2) obtainment of pre-therapy weight and daily weight (3) bedside post-initiation review of therapy by dialysis RN and primary RN to validate therapy orders and fluid removal setting in milliliters, CRRT mode, and circuit connections (4) assessment of patient's response to goal per orders with notification of physician if unstable/unable to tolerate (5) emergency measures, and (6) use of the CRRT flowsheet for procedural documentation. The working procedure was implemented with and acknowledged by the ICU staff via departmental huddles and adopted.

**2/13/2017, 9/14/2017**

#### D. Monitor

Responsible Party: ICU Director

Indicator Description: Audit 100% of the ICU CRRT Flowsheet monthly for documentation compliance with the Continuous Renal Replacement Therapy (CRRT) Policy for dialysis RN and primary RN validation of therapy orders and fluid removal setting in milliliters.

Monthly reporting of results continues until 100% compliance is sustained for 3 consecutive months.

Numerator: The total number of CRRT Flowsheets wherein documentation is compliant with policy.

Denominator: Total number of CRRT Flowsheets reviewed.

Results of audit will be reported to the QA&I Committee, Medical Executive Committee and Governing Board.

**5/1/2019 & ongoing**