STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 000	INITIAL COMMENTS An unannounced onsite survey was conducted 10/31/18 to 11/8/18 to investigate complaint # TN00045852. An entrance conference was held with the Regulatory Officer, Accreditation Specialist and the Senior Quality and Patient Advisor. They were informed of the nature of the complaint. A telephone exit conference was held on 11/8/18 at 2:00 PM. The Regulatory Officer, Accreditation Specialist and the Senior Quality and Patient Advisor, and the Accreditation Regulatory Specialist were notified of Immediate Jeopardy in the areas of 482.13 Patient Rights, 482.23 Nursing Services. They were afforded the opportunity to ask questions of the survey team.	A 000		
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on policy review, medical record review, and interview, the hospital failed to ensure patients' rights were protected to receive care in a safe setting and implemented measures to mitigate risks of potential fatal medication errors to the patients receiving care in the hospital. The failure of the hospital to mitigate risks associated with medication errors and ensure all patients' received care in a safe setting to protect their physical and emotional health and safety placed all patients in a SERIOUS and IMMEDIATE THREAT and placed them in	A 115		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 115	Continued From page 1 IMMEDIATE JEOPARDY and risk of serious injuries and/or death. The findings included: 1. The hospital failed to ensure all patients received care in a safe setting and staff followed standards of practice and utilized their nursing skills and training to ensure the correct medications were administered to all patients. Refer to A-0144 2. The hospital failed to ensure patients were free from neglect. Refer to A-0145	A 115		
A 144	PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2) The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on standards of practice, document review, review of hospital policies and procedures, medical record review, and interview, the hospital failed to ensure all Critical Care Registered Nurses (RN) implemented medication policies and procedures pertaining to the administration and monitoring of medications, including high-risk medications, and patients received care in a safe setting for 1 of 5 (Patient #1) patients reviewed for medication errors. The failure of the hospital to ensure all nurses followed medication administration polices and procedures resulted in a fatal medication error for Patient #1 and placed all patients in a SERIOUS and IMMEDIATE THREAT of their health and	A 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 2	A 144		

safety and placed them in IMMEDIATE JEOPARDY for risk of serious injuries and/or death.

The findings included:

1. Review of the Lippincott Manual of Nursing Practice 10th Edition documented, "...Watch the patient's reaction to the drug during and after administration. Be alert for major adverse effects, such as...respiratory distress...NURSING ALERT...The nurse is ultimately accountable for the drug administered..."

Review of the hospital's High Alert Medications policy documented, "...High Alert Medications - Medications that bear a heightened risk of causing significant patient harm when used in error...Medication orders are reviewed by a pharmacist prior to removal from floor stock or an automated dispensing cabinet unless...A delay would harm the patient (including sudden changes in a patient's clinical status...Additional strategies are followed for a specified list of High Alert Medications...Higher level decision support...Independent Double-Check where electronic clinical systems prompt dual signoff..."

The medication Vecuronium (a neuromuscular blocking medication that causes paralysis and subsequent death if not monitored accordingly) was listed in the policy as a high alert medication. There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

Review of the document ISMP List of High-Alert Medications in Acute Care Settings...ISMP 2018

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 3	A 144		

documented, "...High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error...Classes/Categories of Medications...moderate sedation agents, IV [Intravenous] (e.g.[for example]...midazolam [Versed]...neuromuscular blocking agents (e.g...rocuronium, vecuronium)..."

Review of document Paralyzed by Mistakes: Reassess the Safety of Neuromuscular Blockers in Your Facility documented, "...Neuromuscular blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error...Because neuromuscular blockers paralyze the muscles that are necessary for breathing, some patients have died or sustained serious, permanent injuries if the paralysis was not witnessed by a practitioner who could intervene. After a patient receives a neuromuscular blocker, progressive paralysis develops, initially affecting the small muscle groups such as the face and hands, then moving to larger muscle groups in the extremities and torso until all muscle groups are paralyzed and respiration ceases. However, full consciousness remains intact, and patients can experience intense fear when they can no longer breathe. They can also sense pain. The experience can be horrific for patients...The most common type of error with neuromuscular blockers appears to be administration of the wrong drug...Practitioners thought they were administering a different drug, so patients may not have been supported with mechanical ventilation..."

Review of document titled Joint Commission eyes overrides of dispensing cabinets dated May, 2018

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 4	A 144		

in the American Journal of Health-System Pharmacy documented, "...vice president at the Institute for Safe Medication Practices (ISMP) said her organization has long considered ADC [automated dispensing cabinet] overrides potentially problematic. One of the big problems with automated dispensing cabinets is that sometimes staff are overriding without having an order." she said. "There's no verbal order written down, or they're anticipating an order, so they get a drug from the cabinet"..."

Review of the document titled Evaluation of Medications Removed from Automated Dispensing Machines [ADMs] Using the Override Function Leading to Multiple System Changes documented, "...The override function allows a nurse to remove a medication from the machine before a pharmacist reviews the order. The purpose of the override function is to allow access to medications in urgent/emergent situations...Administering medications prior to a pharmacist review increases the risk of medication errors...The challenge with ADMs is to prevent medication overrides in nonurgent settings and to avoid administering medications from orders that have not been reviewed by a pharmacist..."

Review of the document titled The Drug Summary for Midazolam Hydrochloride (Versed). Retrieved from PDR, 2018, http://www.pdr.net documented, "...CLASSES Anxiolytics Benzodiazepine Sedative/Hypnotics Other General Anesthetics...Administration of midazolam requires an experienced clinician trained in the use of resuscitative equipment and skilled in airway management...Monitor patients for early signs of respiratory insufficiency,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 5	A 144		

respiratory depression, hypoventilation, airway obstruction, or apnea (i.e., via pulse oximetry), which may lead to hypoxia and/or cardiac arrest.

Review of the Centers for Medicare and Medicaid (CMS) Interpretive Guidelines documented, "...Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication. Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously..."

Review of the hospital's policy titled Medication Administration documented, "[Named Hospital] staff validate the five rights of medication administration to minimize medication errors...Right patient; Right medication; Right dose; Right route...Right time to adhere to the prescribed frequency and time of administration...Document medication administration in the electronic medical record to include, at a minimum, the following...Date and time of administration; Medication name and strength; Dosage of medication administered...Route of administration..." There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

2. Medical record review for Patient #1 revealed the patient was admitted to the hospital on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 6	A 144		

12/24/17 with diagnoses of Intraparenchymal Hematoma of the Brain, Headache, Homonymous Hemianopia (vision field loss of both eyes)-Left, Atrial Fibrillation, and Hypertension. The record revealed the patient was awake, alert and oriented and spent time shopping prior to hospitalization.

The record revealed Patient #1 was transported to Radiology for a PET (Positron Emission Tomography) scan on 12/26/17 for a full body scan. The procedure was scheduled for 2:00 PM. There was no documentation in the medical record the time the patient arrived in Radiology. Patient #1 was alert and oriented. While in Radiology Patient #1 requested something for anxiety before the PET scan procedure due to being claustrophobic.

Review of the medication order #60651186 dated 12/26/17 at 3:00 PM revealed the physician ordered Versed 2 milligrams (mgs) intravenously for the patient's anxiety during the PET scan procedure.

Review of the Automatic Dispensing Cabinet (ADC) detail report revealed the order was entered on 12/26/17 at 2:47 PM. Pharmacy had verified the order at 2:49 PM.

Review of the ADC detail report dated 12/26/17 revealed at 2:59 PM Registered Nurse (RN) #1 took the medication Vecuronium 10 mgs (a neuromuscular blocking agent which causes paralysis) from the ADC located in the Neuro Intensive Care Unit (ICU) using the override feature, instead of taking the Versed medication that was ordered for Patient #1. There was no physician order for Patient #1 to receive

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 7	A 144		

Vecuronium. The override was not verified by Pharmacy. There was no documentation in the patient's medical record the RN had administered the Vecuronium to the patient.

Review of a physician note dated 12/26/17 at 3:45 PM revealed the physician documented, "Called for code in PET scanner, patient was pulseless and unresponsive on arrival. patient was emergently intubated and retrieved ROSC [return of spontaneous circulation] after 2 - 3 rounds of chest compressions. Patient transferred to Neuro ICU".

Review of the Nurse Practitioner's (NP) note dated 12/26/17 revealed the NP documented, "Patient was doing well and transferred to the stepdown unit. On 12/26/17, patient was readmitted to NCU [neuro critical care] after suffering cardiac arrest while while off the unit to undergo PET scan..."

Review of the physician's note dated 12/27/17 revealed the physician documented, "I discussed the case with the neurology team and it is felt that these changes in exam likely represent progression towards but not complete brain death...very low likelihood of neurological recovery, we made the decision to pursue comfort care measures. [Patient #1] was made a DNR [do not resuscitate]..." The physician documented the patient was extubated (removed from mechanical ventilation) on 12/27/17 at 12:57 AM and expired on 12/27/17 at 1:07 AM.

3. Telephone interview with RN #1 on 11/5/18 beginning at 4:41 PM, RN #1 was asked to describe the circumstances leading up to Patient #1's death beginning on Tuesday 12/26/17. RN

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

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A 144	Continued From page 8	A 144		

#1 stated, "I was in a patient care role, I was the help-all nurse. A help-all nurse is a resource nurse and I had an Orientee"
RN #1 stated that RN #2 had asked her to go downstairs to Radiology PET scan and administer the medication Versed to Patient #1 because the patient was not able to tolerate the PET scan procedure or they would have to send the patient back and reschedule it.
RN #1 stated he/she searched for the Versed under her profile in the ADC and he/she couldn't find it. The RN stated he/she then chose the override setting on the ADC and searched for the Versed.
RN #1 stated she was talking to the Orientee while he/she was searching the ADC for the Versed and had typed in the first 2 letters of Versed which are VE and chose the 1st medication on the list.
RN #1 stated he/she took out the medication vial out of the ADC, and looked at the back of the vial at the directions for how much to reconstitute it with. RN #1 verified he/she did not re-check the name on the vial.
RN #1 stated he/she grabbed a sticker from the patient's file, a handful of flushes, alcohol swabs, a blunt tip needle. RN #1 stated he/she put the medication vial in a baggie and wrote on the baggie, "PET scan, Versed 1-2 mg" and went to Radiology to administer the medication to Patient #1.
RN #1 was asked how long it took her to get to the Radiology department PET scan, and RN #1 stated, "5 minutes or less, it was my first time to go to PET scan, I had to ask for directions". RN #1 stated, "I saw one patient [who was Patient #1] on one of our beds, I checked the patient for his/her identity, and told her I was there to give him/her something to help him/her relax".

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 9	A 144		

RN #1 stated, "I reconstituted the medication and measured the amount I needed"
The RN stated Radiology Technician #1 was there at the time he/she administered the medication IV to Patient #1. RN #1 stated he/she left the Radiology PET scan area after he/she had administered the medication to Patient #1.
RN #1 was asked how much medication did he/she administer to Patient #1, and the RN stated, "I can't remember, I am pretty sure I gave [him/her] 1 milliliter.
RN #1 was asked what was done with any left over medication, and the RN stated, "I put the left over in the baggie and gave it to [Named RN #2]..."
RN #1 was asked what he/she did after administering the medication to Patient #1, and the RN stated he/she left Patient #1 in Radiology.
RN #1 confirmed that he/she did not monitor Patient #1 after the medication was administered.
RN #1 was asked what happened next and the RN stated, "Patient #1's family was standing outside in the hallway...we heard a rapid response call for PET scan. That was a red flag since the patient was ours, so [Named RN #2] called down there [to the PET scan] but there was no answer. The family looked at us and said "ours?" [Named RN #2] said "we are going to make sure." We tried to call PET scan again, we were being responsible to go to see if it was our patient".
RN #1 stated that he/she and RN #2 went to PET scan and when they arrived Patient #1 was intubated and had regained a heart rate. The RN stated he/she, Physician #2, and the Charge Nurse moved Patient #1 back to the ICU.
RN #1 stated, "I told [Named Physician #2] that I had given [Patient #1] Versed a few minutes ago...I reminded the Nurse Practitioner that

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 10	A 144		

Patient #1 was awake but unmonitored when I gave the Versed".
RN #1 stated RN #2 approached him/her and asked, "Is this the med you gave [named Patient #1]?" and RN #1 responded "yes". RN #1 then stated RN #2 said, "This isn't Versed, It's Vecuronium."
RN #1 stated, went into Patient #1's room and informed Physician #2, and the NP that he/she had made a mistake and administered Vecuronium to Patient #1 instead of Versed.
RN #1 was asked if it was documented he/she had administered the Vecuronium in Patient #1's medical record. RN #1 stated, "I did not. I spoke with [Named Nurse Manager] and he/she told me the new system would capture it on the MAR [Medication Administration Record]. I asked and [the Nurse Manager] said it would show up in a special area in a different color."
RN #1 was asked if he/she could remember how much Vecuronium she administered to Patient #1, and RN #1 stated, "I would have given 1 milligram."
RN #1 was asked if he/she talked to anyone at the hospital in the days after the event, and the RN stated, "I did have some conversations with risk management. I don't remember all I said. It was on the phone. I came back on the 3rd [January] and saw [Named Nurse Manager]. That is when I was terminated. They sent me to an employee resource counsellor for my own personal wellbeing."
RN #1 was asked about the "help-all nurse" role and was there documentation of what was done while working a shift, and the RN stated, "If you do something, you just chart it for that patient". The RN stated there was not an actual job description for the role of a "help-all nurse"

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 11 4. Interview with Radiology Technician (RT) #2 on 11/2/18 at 1:30 PM the RT was asked about the events surrounding [Named Patient #1's] medication error in December. RT #2 stated, "[Patient #1] was an inpatient brought down by Transport, and was dropped off in a hallway. Me and another girl went to get the patient and put in an injection room. [Patient #1] said he/she was claustrophobic so the other girl called the patient's nurse...a transporter walked by the patients room and noticed he/she was unresponsive. We were in the control room, we have cameras that we can view but not to the point of seeing if they are breathing." RT #2 was asked how long the patient was in the room by him/herself before the transporter noticed him/her. RT #2 stated, "If I was going to guess, maybe 30 minutes. I don't know specifically. I ran to call the code and [Named RT #1] started CPR..." Telephone interview on 11/5/18 at 9:29 AM with RN #2 (Patient #1's primary care nurse prior to the Event) the RN #2 was asked to describe the events surrounding Patient #1's death. RN #2 stated, "...[Patient #1] was scheduled for a PET scan and was nervous...PET scan called me and told me the doc [doctor] had ordered an IV med [medication] for anxiety...I relayed to the help all nurse and [Named RN #1] agreed to go and administer it. I don't remember the timing, I heard the code, they brought [Patient #1] back to an ICU room. I went over to ICU to give report to the nurse taking care of the patient and [Named RN #1] handed me a vial in a bag...I went back to my desk to do some charting and then I realized it [Vecuronium had been administered instead of Versed] I went and told my charge nurse and I gave the bag to him/her. That was the end of my	A 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 12	A 144		

involvement."
RN #2 was asked how long he had the bag with the vial in it before he/she realized it was the wrong medication. RN #2 stated, "It was less than 15 minutes..."

Telephone interview with RT #1 on 11/5/18 beginning at 1:15 PM he/she was asked about the events that lead up to Patient #1's death, and RT #1 stated, "Transportation brought [Patient #1] in and I talked to [Patient #1] about the scan. He/She said he/she needed some medication for anxiety and he/she had gotten some when he/she had an MRI. I called [Patient #1's] nurse to let him/her know and the doctor that she could not go through the scan, so the doctor ordered Versed. We had a busy day that day, it was a full schedule. We were going to send [Patient #1] back if they couldn't come and give him/her the med. [Patient #1's] nurse asked if our nurses could give it, so I asked them and they said no because the patient would need to be monitored. I then asked [the patient's] nurse if he/she would need to be monitored and he/she said no and he/she would send another nurse. I injected the [radioactive] tracer for the scan knowing she was going to get the medication. We can't do the PET scan for an hour after the tracer is injected so it can circulate throughout the body. Two nurses came down and he/she asked if this was the patient that needed the med. [The nurse] gave the med and then we put [the patient] into our patient room. That is where they wait the hour. I went back into the scan room. Sometime later, the transporter was there to pick up [Named Patient #1], he found him/her unresponsive, we called the rapid response, I started chest compressions and [Named RT #2] got the crash cart..."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 144	Continued From page 13 RT #1 was asked about how long Patient #1 was in the room after the nurse came and administered the medication, and RT #1 stated, "I had briefly 30 minutes of uptake time left. We could see him/her through the camera from where we were. He/She had her eyes closed the entire time, we thought it was a light issue with her eyes. The camera isn't sharp enough to pick up breathing. [rise and fall of the chest]" RT #1 was asked if Patient #1 was monitored after receiving the medication for anxiety, and RT #1 stated that the RN #1 did not stay and monitor the patient after he/she administered the medication.	A 144		
A 145	PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT CFR(s): 482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based on standard of practice, document review, review of hospital policies and procedures, interpretative guidances, Review of Tennessee Code Annotated, medical record review and interview, the hospital failed to ensure patients were free from all forms of abuse when a Critical Care Registered Nurse (RN) neglected to administer medication as ordered to 1 of 5 (Patient #1) sampled patients review for medication errors and failed to monitor for any untoward effects as the patient experienced respiratory/cardiac arrest. The hospital failed to report this incident to the Tennessee Department of Health as mandated. The failure of the nurse to administer the	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 14	A 145		

medication as ordered and to ensure the patient was monitored for untoward effects resulted in a SERIOUS and IMMEDIATE THREAT to the health and safety of all patients and placed them in IMMEDIATE JEOPARDY and risk of serious injuries and/or death.

The findings included:

1. A review of the "Lippincott Manual of Nursing Practice 10th Edition" documented, "...Watch the patient's reaction to the drug during and after administration. Be alert for major adverse effects, such as...respiratory distress...NURSING ALERT...The nurse is ultimately accountable for the drug administered..."

A review of the "ISMP List of High-Alert Medications in Acute Care Settings...ISMP 2018" documented, "...High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error...Classes/Categories of Medications...moderate sedation agents, IV [Intravenous] (e.g.[for example]...midazolam [Versed]...neuromuscular blocking agents (e.g...rocuronium, vecuronium)..."

2. Review of "Paralyzed by Mistakes: Reassess the Safety of Neuromuscular Blockers in Your Facility" documented, "...Neuromuscular blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error...Because neuromuscular blockers paralyze the muscles that are necessary for breathing, some patients have died or sustained serious, permanent injuries if the paralysis was not witnessed by a practitioner who could intervene.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 15 After a patient receives a neuromuscular blocker, progressive paralysis develops, initially affecting the small muscle groups such as the face and hands, then moving to larger muscle groups in the extremities and torso until all muscle groups are paralyzed and respiration ceases. However, full consciousness remains intact, and patients can experience intense fear when they can no longer breathe. They can also sense pain. The experience can be horrific for patients...The most common type of error with neuromuscular blockers appears to be administration of the wrong drug...Practitioners thought they were administering a different drug, so patients may not have been supported with mechanical ventilation..." 3. A review of the hospital's "High Alert Medications" policy documented, "...High Alert Medications - Medications that bear a heightened risk of causing significant patient harm when used in error...Medication orders are reviewed by a pharmacist prior to removal from floor stock or an automated dispensing cabinet unless...A delay would harm the patient (including sudden changes in a patient's clinical status...Additional strategies are followed for a specified list of High Alert Medications...Higher level decision support...Independent Double-Check where electronic clinical systems prompt dual signoff..." Vecuronium was listed as a high alert medication. There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered. Review of the facility's "Medication Administration" documented, "[Named Hospital] staff validate the five rights of medication	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 16	A 145		

administration to minimize medication errors...Right patient; Right medication; Right dose; Right route...Right time to adhere to the prescribed frequency and time of administration...Document medication administration in the electronic medical record to include, at a minimum, the following...Date and time of administration; Medication name and strength; Dosage of medication administered...Route of administration..."
There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

Review of the hospital's "Interpretive Guidelines for Reportable Events" revised July 2009 revealed, "Effective May 27, 2009, the Health Data Reporting Act of 2002 was amended by Public Acts of 2009, Chapter 318. The new law provides that all licensed health care facilities...shall only report incidents of abuse, neglect, and misappropriation that occur at the facility to the Department. For state licensure purposes, the facility is required to make the report within seven (7) business days from the date that the facility identifies the incident... Definitions... 'Neglect' means the failure to provide goods and services necessary to avoid physical harm..."

4. Review of State Operations Manual, Appendix A Survey Protocol, Regulations, and Interpretative Guidelines for Hospitals revealed, "...482.13(c)(3)... The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff... The hospital must ensure that patients are free from all forms of abuse, neglect, or harassment... Neglect... is

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 17	A 145		

considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. The following components are suggested as necessary for effective abuse protection... Report/Respond. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs..."

The "RULES OF TENNESSEE DEPARTMENT OF HEALTH BOARD FOR LICENSING HEALTH CARE FACILITIES CHAPTER 1200-08-01 STANDARDS FOR HOSPITALS " documented on page 31, "...(6) Pharmaceutical Services...(d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies..."

5. The "Tennessee Code Annotated Title 71...Chapter 6...Part 1..." documented, "...71-6-103...Any person, including, but not limited to, a physican, nurse...having reasonable cause to suspect that an adult has suffered...neglect...shall report or cause reports to be made in accordance with this part. Death of the adult does not relieve one of the responsibility for reporting the circumstances surrounding the death...If a hospital...or any other organization or agency responsible for the care of adults has a specific procedure, approved by the director of adult protective services for the department, or the director's designee, for the protection of adults who are victims of...neglect...any member

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 18	A 145		

of its staff whose duty to report under this part arises from the performance of the staff member's services as a member of the staff of the organization may, at the staff member's option, fulfill that duty by reporting instead to the person in charge of the organization or the organization head's designee who shall make the report in accordance with this chapter...An oral or written report shall be made immediately to the department upon knowledge of the occurrence of suspected...neglect...of an adult..."

The "Tennessee Code Annotated Title 68...Chapter 11...Part 2..." documented, "...68-11-211...Reporting incidents of abuse, neglect...As used in this section..."Department" means the department of health..."Facility" means any facility licensed under this part..."Neglect" means the failure to provide goods and services necessary to avoid physical harm...each facility shall report incidents of...neglect...that occur at the facility to the department within seven (7) business days from the facility's identification of the incident...Nothing in this section shall be construed to eliminate or alter in any manner the required reporting of...neglect...or any other provisions of...title 71, chapter 6, part 1..."

6. Patient #1 was admitted to the hospital on 12/24/17 with diagnoses of Intraparenchymal Hematoma of the Brain, Headache, Homonymous Hemianopia (vision field loss of both eyes)-Left, Atrial Fibrillation, and Hypertension.

Patient #1 was transported to Radiology for a P.E.T. (Positron Emission Tomography) scan on 12/26/17 for a full body scan. The procedure was scheduled for 2:00 PM. Patient #1 was alert and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 19	A 145		

oriented to person, place, time and situation. While in Radiology, Patient #1 requested something for anxiety before the PET scan procedure due to being claustrophobic.

Review of medication order #60651186 order details dated 12/26/17 at 3:00 PM, revealed Versed (Midazolam) 2 mg. (milligrams) intravenous one time. Administration instructions documented, "For PET scan if first milligram insufficient, can give 1-2mg additional if needed..." Review of the Automatic Dispensing Cabinet (ADC) detail report revealed the order was entered on 12/26/17 at 2:47 PM. Pharmacy verified the order at 2:49 PM. Versed was not removed from the Automated Dispensing Cabinet (ADC).

Review of medication order #60651187 order details dated 12/26/17 at 3:00 PM, revealed Versed (Midazolam) 1 mg. intravenous one time. Administration instructions documented, "For PET scan" Review of the Automatic Dispensing Cabinet (ADC) detail report revealed the order was entered on 12/26/17 at 2:47 PM. Pharmacy verified the order at 2:49 PM. Versed was not removed from the ADC.

Review of the ADC detail report dated 12/26/17 revealed Vecuronium (a paralytic drug) 10 mg. injection was pulled at 2:59 PM from the ADC located in the Neuro ICU using the override feature. There was no physician order for Patient #1 to receive this drug. The order was not verified by Pharmacy.

Review of the time line for the medication error event that occurred on 12/26/17 revealed the following:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 20	A 145		

Patient #1 was scheduled for a PET scan at 2:00 PM.
No documentation when Patient #1 arrived in Radiology.
An order for Versed was entered into the computer at 2:47 PM and was verified by Pharmacy at 2:49 PM. (Versed was available at 2:49 PM under Patient #1's profile)
An override pull for Vecuronium was documented at 2:59 PM.
There is no documentation of the administration time or amount of Vecuronium to Patient #1.
RN #1 stated it took about 5 minutes to get to Radiology before he/she administered it.
Patient #1 was found unresponsive and pulseless in the Radiology Department prior to the PET scan.
A rapid response (Hospital term for emergency resuscitation) was called overhead at 3:29 PM. (30 minutes between the time the drug was pulled from the ADC in Neuro Unit and the time the rapid response was called.

Interview with the Regulatory Officer (RO) and the Senior Quality and Patient Advisor (SQPA) on 10/31/18 at 1:40 PM, they were asked why this event wasn't reported to the state. The RO stated, "I will ask Risk about that because it was a death and it should have been reported."

Interview with the SQPA on 10/31/18 at 3:02 PM, the SQPA stated, "I talked to Risk Management about reporting to the state, and [he/she] stated we [Risk Management] follow the 2009 state rules on reporting and it includes abuse, any, exploitation, fire with disruption of service, strikes, external disasters, misappropriation and injury of a patient in a nursing home of unknown nature. [He/She] said for you to see the state regs

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 21 [regulations], page 31, 6d." Interview with the Manager of Adult Patient Safety Team (MAPST) on 11/1/18 at 4:23 PM, the MAPST stated, the hospital had performed an Event Analysis with the findings are "...The timeline was: 12/26/17 - 2 PM: PET scan scheduled. 12/26/17 - 2:47 PM: 2mg. of Versed was ordered. 12/26/17 - 2:59 PM: Vecuronium override in Acudose. VE was entered in the Acudose and the machine defaults to generic medications - Vecuronium popped up. Versed [brand name] did not show on the screen. A warning in red box was visible for an override stating that is should be for STAT orders. 12/26/17 - RN #1 gave the medication - it's unknown what time she got to Radiology. 12/26/17 - RRT was called at 15:29 [3:29 PM]. STATS go overhead. As a group [leaders, risk etc] what can we do to fix it...Action plan: The bar code scanning implementation in Radiology - this is pending. A Multi-disciplinary team meeting regarding the override med list. Vec [Vecuronium] was removed from override status..." Telephone interview with RN #2 (Patient #1's primary care nurse prior to the Event) on 11/5/18 beginning at 9:29 AM, RN #2 was asked to describe the events surrounding [Named Patient #1's] death. RN #2 stated, "...[Patient #1] was scheduled for a PET scan and was nervous...I was watching another nurse's patients because [the patient's nurse] had gone to lunch. PET scan called me and told me the doc [doctor] had ordered an IV med for anxiety and could I come down and give it to her. I told them I could not come down and could their nurses give it. They said they didn't feel comfortable administering it	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 22	A 145		

and needed a nurse from our floor to come down. I relayed to the "help all nurse" and [Named RN #1] agreed to go and administer it. I don't remember the timing, I heard the code, they brought her back to an ICU room..."

Telephone interview with the Director of Investigations (DOI) at the Medical Examiner's Office on 11/5/18 at 10:01 AM, the DOI was asked about (Named Patient #1) and what was reported to them regarding [Patient #1's] death. The DOI stated, "The date of death was 12/27/17 and was called in by [Named Physician #1]. He/she stated that maybe there was a medication error but that was just hearsay, and nothing has been documented in the medical record. There was no named drug in the notes. The death certificate says [Patient #1] had a bleed. We declined jurisdiction because there was an MRI that confirmed the bleed..."

Telephone interview with RN #1 on 11/5/18 beginning at 4:41 PM, RN #1 was asked to describe the circumstances leading up to Patient #1's death on Tuesday 12/26/17. RN #1 stated, "I was in a patient care role, I was the "help-all nurse". A help-all nurse is a resource nurse and I had an Orientee... [Named RN #2] asked me to go downstairs to PET scan and give [Named Patient #1] Versed because [the patient] was not able to tolerate it [the PET scan procedure] or they would have to send her/him back and reschedule it. We were already heading to ER to do a swallow study on a patient. I went and searched for the med under [the patient's] profile [in the ADC] and it was not there. I chose the override setting and I searched for it. I was talking to the Orientee about why we do swallow studies in the ER...I typed in the first 2 letters [VE] and

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 23	A 145		

that's how I hit it, I chose the 1st one on the list. I took out the vial and I looked at the back at the directions for how much to reconstitute it with, I did not re-check the name on the vial... I saw 1 patient on one of our beds, I checked the patient for his/her identity, and told [the patient] I was there to give him/her something to help him/her relax... I reconstituted it and measured the amount I needed... One of the techs [Radiology Technician #1] came out, I gave the med, flushed it and we left. [Radiology Technician #1] took the patient back. We went straight to the ER from there... I am not sure if I drew up and gave him/her what she needed... heard a rapid response call for PET scan. That was a red flag since out patient was ours... we were being responsible to go to see if it was our patient... when we got there they had intubated him/her and got a pulse back. [Named Physician #2, Named Charge Nurse] myself and the team, we collectively moved him/her bed back to the unit. I told [Named Physician #2] that I had given [the patient] Versed a few minutes ago...I reminded the Nurse Practitioner that Patient #1 was awake but unmonitored when I gave him/her the Versed. We spent probably about 45 minutes getting labs and things. I had drawn several tubes of blood for labs when [Named RN #2] came up to me and he/she said, "Is this the med you gave him/her?" I said yes, we need to waste it. RN #2 stated, "This isn't Versed" I said what is it? He/she said, "It's Vecuronium" and I went back into the room [Patient #1's] and [Named Physician #2], a couple of residents, and [Named Nurse Practitioner] were in the room discussing what was happening. I told them right then it was my mistake. I told them I gave Vecuronium. They all knew it right then. [Named Nurse Practitioner] said, "I'm so sorry" and I left the room. I am not sure where I

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 145	Continued From page 24 went but I ended up in the educators office. I spoke to management - different people. I filled out the "Veritas" [Hospital's reporting system]. This was around four-ish [4:00 PM]. I gave both my phones to the charge nurse and the Orientee was assigned to someone else. It was after 8:00 PM when I left." RN #1 was asked if he/she documented the Vecuronium in Patient #1's medical record. RN #1 stated, "I did not. I spoke with [Named Nurse Manager] and he/she told me the new system would capture it on the MAR [Medication Administration Record]. RN #1 stated that he/she left Patient #1 in Radiology. RN #1 confirmed that he/she did not monitor Patient #1 after the medication was administered.	A 145		
A 286	PATIENT SAFETY CFR(s): 482.21(a), (c)(2), (e)(3) (a) Standard: Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors. (2) The hospital must measure, analyze, and track ...adverse patient events ... (c) Program Activities ..... (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. (e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and	A 286		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 25 administrative officials are responsible and accountable for ensuring the following: ... (3) That clear expectations for safety are established. This STANDARD is not met as evidenced by: Based on standards of practice, document review, review of hospital policies and procedures, medical record review, and interview, the hospital failed to ensure that the Quality Assurance and Performance Improvement (QAPI) program thoroughly analyzed a critical adverse event and all the causes, and implement preventive actions that included adding additional safety parameters associated with overriding paralytics and other High Alert medications from an automated dispensing cabinet (ADC) to ensure that a similar critical adverse event could not reoccur. This failed practice had the potential to affect the safety and health of all patients receiving care in the critical care areas in this hospital. The findings included: 1. Review of the hospital's High Alert Medications policy documented, "...High Alert Medications - Medications that bear a heightened risk of causing significant patient harm when used in error...Medication orders are reviewed by a pharmacist prior to removal from floor stock or an automated dispensing cabinet unless...A delay would harm the patient (including sudden changes in a patient's clinical status...Additional strategies are followed for a specified list of High Alert Medications...Higher level decision support...Independent Double-Check where electronic clinical systems prompt dual signoff..." Vecuronium was listed as a high alert medication.	A 286		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 26	A 286		

There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

Review of the document ISMP List of High-Alert Medications in Acute Care Settings...ISMP 2018 documented, "...High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error...Classes/Categories of Medications...moderate sedation agents, IV [Intravenous] (e.g.[for example]...midazolam [Versed]...neuromuscular blocking agents (e.g...rocuronium, vecuronium)..."

The hospital's document titled High Alert Medications Chart: Adult Patients Revised May 2018 did not list any moderate sedation agents such as Versed.

Review of "Paralyzed by Mistakes: Reassess the Safety of Neuromuscular Blockers in Your Facility" documented, "...Neuromuscular blocking agents are high-alert medications because of their well-documented history of causing catastrophic injuries or death when used in error...Because neuromuscular blockers paralyze the muscles that are necessary for breathing, some patients have died or sustained serious, permanent injuries if the paralysis was not witnessed by a practitioner who could intervene. After a patient receives a neuromuscular blocker, progressive paralysis develops, initially affecting the small muscle groups such as the face and hands, then moving to larger muscle groups in the extremities and torso until all muscle groups are paralyzed and respiration ceases. However, full consciousness remains intact, and patients

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 27	A 286		

can experience intense fear when they can no longer breathe. They can also sense pain. The experience can be horrific for patients...The most common type of error with neuromuscular blockers appears to be administration of the wrong drug...Practitioners thought they were administering a different drug, so patients may not have been supported with mechanical ventilation..."

Review of the document titled Joint Commission eyes overrides of dispensing cabinets dated May, 2018 in the American Journal of Health-System Pharmacy documented, "...vice president at the Institute for Safe Medication Practices (ISMP)said her organization has long considered ADC overrides potentially problematic. "One of the big problems with automated dispensing cabinets is that sometimes staff are overriding without having an order." she said. "There's no verbal order written down, or they're anticipating an order, so they get a drug from the cabinet"..."

Review of the document titled Evaluation of Medications Removed from Automated Dispensing Machines (ADMs) Using the Override Function Leading to Multiple System Changes documented, "...The override function allows a nurse to remove a medication from the machine before a pharmacist reviews the order. The purpose of the override function is to allow access to medications in urgent/emergent situations...Administering medications prior to a pharmacist review increases the risk of medication errors...The challenge with ADMs is to prevent medication overrides in nonurgent settings and to avoid administering medications from orders that have not been reviewed by a pharmacist..."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 28 2. Observations in Neuro Critical Care Unit (NCU) on 11/1/18 beginning at 1:38 PM revealed the ADC that was used to withdraw medications in the Neuro Unit. The NCU Pharmacist was at the ADC and demonstrated how medication is withdrawn. The NCU Pharmacist was asked to show how the paralytic drug Rocuronium is stored and how to remove it through the override function. The ADC was accessed by the pharmacist's fingerprint. The Pharmacist entered "RO" and Rocuronium was displayed on the screen. He/She chose that drug and the drawer opened. There were 3 vials of Rocuronium in the bin. The bin was labeled with an orange sticker that documented, "WARNING: Paralyzing Agent Causes Respiratory Arrest." The Pharmacist was asked if Rocuronium could be overridden. He/She confirmed Rocuronium could be overridden because of the emergent need of the drug during a rapid response. 3. Interview with the Manager of the Adult Patient Safety Team (MAPST) on 10/31/18 beginning at 3:15 PM, in conference room 167, the MAPST was asked about his/her role regarding the events associated with Patient #1, and the MAPST stated, "We facilitate Event Analysis here - it used to be called Root Cause Analysis, regarding the medication error, we [a multidisciplinary group] did the root cause analysis. We learned the nurse and the Orientee were called to Radiology for a patient that was having some anxiety. [Patient #1] was in the Neuro stepdown unit but waiting for a floor bed. [RN #1] pulled the med from ICU. He/She went into the system and picked the patient and typed "VE" for Versed and did a search. He/She chose Vecuronium because it was the first that came	A 286		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 29	A 286		

up. The window popped and alert up notifying that drug was not in the patient's profile and she over rode that, which can be done due to possible emergencies. This drug was a powder and had to be reconstituted, Versed did not [have to be reconstituted]. Reconstitution was a question of where was it done. He/She gives the drug to the patient and left the patient unattended. The radiology team called her down to help and give the Versed."
The MAPST was asked how long was [the patient] was left unattended, and the MAPST stated, "They found her in arrest, called the code. I don't know how long it was between when the med was given and the code was called...We looked at the medications that are on override and took Vecuronium out of override status. [Named Quality Pharmacist] was part of this meeting." The MAPST was asked if any education was done for the nursing staff. The MAPST stated, "Safe transport education - making sure if a patient needs meds, they have the appropriate staff with them and Neuro added a sedation review to their annual competencies'.

Interview with the Provider Support Services Representative (PSSR) on 10/31/18 at 3:30 PM, in conference room 167, the PSSR was asked if there was any discussion at any meeting after the event occurred in December, 2017. As the PSSR reviewed the minutes for each monthly meeting Med Executive Meeting from January through October 2018, the PSSR stated, "We do the credentialing for all the providers and we coordinate the minutes for the Med Executive Meeting. [Medical Center Medical Board]. The review of the minutes on January 11, 2018 revealed a new policy called Medication Ordering was presented at this meeting. The process for

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 30	A 286		

removing meds from the Acudose [Automated Dispensing Cabinet] was not listed on the minutes meeting agenda for January through October [2018]." The PSSR was asked if there was any discussion during any of the Executive Committee meeting minutes regarding the process for obtaining medications from the ADC. The PSSR reviewed the monthly meeting minutes from January through August 2018, and the PSSR stated, "There was a Medication Administration policy updated at the May meeting and was discussed, approved and passed unanimously in the June meeting."
There was no evidence or documentation this medication error was discussed in the Med Executive meetings or the Executive Committee meetings.

Interview with Pharmacist #1 (Medication Safety Program Director) on 11/1/18 at 4:00 PM, in conference room 167, Pharmacist #1 was asked if he/she knew where the vial of Vecuronium was that was used when the medication error occurred in December, 2017, and he/she stated, "It's my understanding the vial was not quarantined in time. We cannot tell how much she got, that's my understanding."
He/She was asked if reversing agents are readily accessible, and Pharmacist #1 stated, "Sugammadex [a neuromuscular reversal drug] we have that on formulary, it's available in the ORs [Operating Rooms] where paralytics are used the most. In an ICU area, that would have paralytics, it would have to come through Anesthesia...We no longer use Vecuronium for RSI [Rapid Sequence Intubation]. There was a global review and we now use Rocuronium."
He/She was asked if Rocuronium is still available on override in Neuro ICU, and the Pharmacist

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 31	A 286		

stated, "Yes, the decision was made to continue, it has that level of access and because of the urgency of the need." He/She further stated, "We rolled out EPIC, our new system for documentation last year in November [2017]. We did an expansion with the bar code scanners to the ED [Emergency Department], PACU [Post Anesthesia Care Unit], Holding Rooms and Radiology is next. It was already on the list [roll out]."

Interview with the MAPST and the SQPA on 11/1/18 at 4:23 PM, the MAPST stated, "We use the Safety Event Decision Algorithm as part of our methodology...overview of the EA: He/She had a lengthy intolerance to lengthy procedures. The Neuro Primary Nurse asked the help-all nurse to administer the medication. The med was administered without being scanned into the patient's EMR [Electronic Medical Record]. The time frame between administering the Vec [Vecuronium] in Radiology and the time the RRT [Rapid Response Team] was called remains in question. [Named RN #1] made her way back to [Named Primary Nurse's] assignment. He/She handed him the bag with the vial in it. The RRT phone went off announcing for patient in PET 1251. [Named RN #1 and RN #2] went to the PET area and found the patient she had given the med to. [Named RN #1] helped the team transport him/her back to NCU. After he/she got back, [Named RN #2] asked him/her if this [holding the bag] was what he/she gave the patient. He/She confirmed it was. [Named RN #1] asked [Named RN #2] to give it [the bag and the med in it] to the charge nurse to address the issue. We don't know who the charge nurse was or what he/she did with the medication. [Named RN #1] notified the team [team of doctors, NP] in

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 32	A 286		

[Patient #1's] room what had occurred. He/She also notified the charge nurse, the CSL [Clinical Staff Leader] and went to the educator's office. He/She notified [Named Neuro Nurse Manager] and Risk Management...The timeline was:
12/26/17 - 2 PM: PET scan scheduled.
12/26/17 - 2:47 PM: 2mg. of Versed was ordered.
12/26/17 - 2:59 PM: Vecuronium override in Acudose. VE was entered in the Acudose and the machine defaults to generic medications - Vecuronium popped up. Versed [brand name] did not show on the screen. A warning in red box was visible for an override stating that is should be for STAT orders.
12/26/17 - RN #1 gave the medication - it's unknown what time she got to Radiology.
12/26/17 - RRT was called at 15:29 [3:29 PM]. STATS go overhead.
As a group [leaders, risk etc] what can we do to fix it...Action plan: The bar code scanning implementation in Radiology - this is pending. A Multi-disciplinary team meeting regarding the override med list. Vec [Vecuronium] was removed from override status. Roc [Rocuronium] was left on [the override list] for emergencies. We weighted the risks versus the benefits and left it on. We met on January 19. The meeting on February 2, it was approved. The meeting on February 23 was the Pharmacy Policy Committee. The meeting on March 3 it was completed...We also did education of local [NCU] and global nursing team members regarding sedative administration and monitoring..."

Interview with SQPA on 11/2/18 at 9:22 AM, she stated, "...we wanted to make sure the Patient Safety Alert from the Safety Team went to operational leaders and [Named VUH CNO] was a recipient of this alert and she sends out the

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 33	A 286		

information to her reports..."

Review of the time stamp on the "Patient Safety Notification Serious Safety Event Notification revealed the notification was distributed on Wednesday, 1/3/18 (8 days after the event occurred). The notification documented, "[Patient #1's Initials], was a 75 y.o. [year old] female admitted for ICH [Intracerebral Hemorrhage]. Versed 1 mg IV ordered to assist with patient comfort during PET scan. Vecuronium 1 mg IV inadvertently retrieved and administered by RN. Due to neurological sequelae, pt. placed on comfort care by family and died later that day. A serious safety event analysis (SSEA) is in progress of being convened. Please contact the QSRP Safety Team, at [telephone number], if you need additional information."

4. Interview with the Director for Clinical Risk Management (DCRM) on 11/2/18 at 12:35 PM, in conference room 167, the DCRM produced the baggie with the medication in it. She stated, "My understanding is this is the actual baggie..." The DCRM was asked if he/she spoke to RN #1 and was he/she able to explain the contents. The DCRM stated, "He/She took this with him/her [holding up the baggie]. The nurse stated this was the syringe with the drug in it that that was administered to the patient in PET. [holding up the syringe with the 1.5 mL clear liquid in it]...He/She was distraught and it was a small window to get the information...We are not sure what is in each syringe, this package was the waste possibly [holding up the baggie]...the level of granularity in our investigation, 2 things were happening, the patient's clinical needs, during the arrest we identified the wrong drug. The family was told immediately of a possible med error. On

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 34	A 286		

our end, we put the med in a secure place. We also try to give the employee assistance. By the time they pronounced [Patient #1], they thought it was the VEC [Vecuronium] and we will get back with you [the family]. There was a med error that likely impacted her breathing. We are very up front early on. Then Risk and Quality began to look at the Pyxis [ADC], looking to see if something is wrong with the machine. In the end, there were so many things the nurse did - the 5 rights, basic nursing care. I had reached out to the family and they had already obtained an attorney - and the rest is confidential...assessment before [medication given], 5 rights give med and assess after" The DCRM was asked about the lack of documentation in the chart. He/She stated, "Everyone was focused on resuscitation. The code team was called, they treated only the resuscitation. The investigation was after she was dead. He/She was worked on and at no time was he/she stable. There was no opportunity for her [RN #1] to chart about the med."

Observations in conference room 167 on 11/2/18 at 12:35 PM revealed one (1) clear zip lock baggie with an orange biohazard label. There was handwriting on the baggie in a pink color marker that documented, "Versed 1mg 2mg PET 1251." Inside the baggie was a vial with a few drops of clear liquid remaining in the vial. The vial was labeled Vecuronium Bromide 10mg. 1mg/mL when reconstituted to 10mL. Reconstitute with Bacteriostatic water. The vial had a red top that documented, "WARNING: PARALYZING AGENT." There was one (1) 10 mL syringe labeled "Normal Saline" with a capped needle attached. The syringe had 8 mL of a clear liquid remaining in it. There was one 10 mL syringe

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 35	A 286		

labeled "Normal Saline" with 1.5 ml of a clear liquid remaining in it and capped with a white cap with no needle. There was also a 2" alcohol prep pad in the baggie.

There was no way to tell what was Vecuronium and what was normal saline and no way to determine how much of the drug Patient #1 actually received.

5. Interview with the Regulatory Officer (RO) on 11/6/18 at 12:57 PM, in conference room 167, he/she was asked what is the process for incidents, and the RO stated, "The occurrence happens, then its logged into the system [Veritas II- reporting software], a review is made with Risk and Quality, if there is a chance it is serious, it goes to the executive leadership for review, then if it is, a serious safety event is released and sent down to all staff. In the background we are doing the investigative portion - the event analysis [EA]. We took and take immediate action on all events. He was asked why Rocuronium is still available in the Acudose for override, and the RO stated, "An analysis was done for each drug looking at the risks versus the benefits and Rocuronium was left on the override list."
He/she was asked what process has been put in place to ensure this won't happen with Rocuronium, and the RO stated, "Let's get the pharmacist in here to answer that...EA is considered a QAPI"

Interview with the Pharmacy Manager, Pharmacist #2, and the RO on 11/6/18 at 3:06 PM, in conference room 167, he/she was asked what process has been put in place to ensure this won't happen with Rocuronium. The Pharmacy Manager stated, "We felt we had appropriate

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 36	A 286		

safety measures in place. We did a comprehensive review of the override list and removed some of the drugs in a few specific places. Rocuronium has a quicker onset in the body."
The RO stated, "A full analysis was done and there were more safety concerns of putting more safety restrictions due to the need of immediate access. The risk of delay of accessing Roc could lead to negative patient outcomes. Those potentials outweigh the need for additional safety mechanisms."
The Pharmacy Manager stated, " Rocuronium is a generic name which would default on the Acudose machine when putting it in, making it visible on the screen, whereas Versed is a name brand and putting in VE would not display unless the nurse physically pushed the brand name selection."
The RO stated, "The number of safety points this nurse went through was numerous." The RO was asked why was there a delay in nursing education.
The RO stated, "We see the issue and we probably should have educated sooner. We wanted to make sure we did a root cause analysis before we trained on it. We got the alerts out immediately to all staff."
The RO was asked if he looked at the "Help-all nurse's" role, and what areas would he/she be pulled to, and also orienting a new nurse at the same time.
The RO stated, "I have never heart that term, that is not a [Named Hospital] wide term. But believe me, we are going to look at it."
The RO was asked about the process for QAPI and where does the analysis begin and does it get to the system level for review.
The RO stated that each hospital [Adult,

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 286	Continued From page 37 Children's, Behavioral] has committees that meet and review all events. Those committees roll up to each hospital QAPI committee that is chaired by the CEO of that hospital. [see system flowsheet] Each of those committees meet and those meeting minutes are funneled up to the System's Quality Steering Committee which is chaired by the Hospital System's CEO". The Pharmacy Manager stated, "Drug errors are forwarded to QSRP [Quality, Safety , Risk Prevention]. The errors that happened in October will be reported to ADE [Adverse Drug Events] Committee. They meet monthly and will review the October errors this Friday. They meet the second Friday of every month." 6. Review of the education records revealed the education began in March 2018, more than 2 months after the event.	A 286		
A 364	AUTOPSIES CFR(s): 482.22(d) The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. This STANDARD is not met as evidenced by: Based on document review, review of hospital policies and procedures, medical record review, and interview the hospital failed to ensure all physicians followed policies, and rules and regulations for reporting unusual and unexpected deaths to the County Medical Examiner for 1 of 1	A 364		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 38 (Patient #1) patient deaths reviewed. The findings included: 1. Review of the hospital's Deaths Requiring Reporting to the Medical Examiner policy documented, "...The Davidson County ME [Medical Examiner] is notified of all deaths occurring at [Named Hospital System] that require reporting to the ME prior to discussions with the patient's family regarding an autopsy for a reportable death, as stated in Section IIIA...Deaths reportable under Tennessee law and [Named Hospital] policy include ALL those due to, apparently due to, related to, or admitted for the following (regardless of the interval between event and time of death)...Any suspicious, unusual or unnatural death...Death during or as a result of a...medication error...It is the responsibility of the physician completing the Report of Death...to notify the Davidson County ME when a death falls within any of the categories described above. In case of uncertainty of the need to report a death, the ME is consulted regarding whether or not the death is reportable. The ME makes the final determination of case acceptance for examination..." Review of the hospital's Medical Staff Rules and Regulations documented, "...Deaths...[Named Hospital System] complies with all applicable state and local law regarding certification of death...and the reporting of deaths to the medical examiner under circumstances required by state law to facilitate the performance of inquests in accordance with hospital policy...Medical Examiner Cases...The physician...in charge of the patient's care for the...condition that resulted in the patient's death shall report any death due to,	A 364		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 39	A 364		

apparently due to...regardless of the interval between event and time of death to the...Medical Examiner's Office..."

Review of the hospital's House Staff Agreement... signed by Physician #3 documented, "...In accepting this appointment, I hereby agree to...Abide by the applicable Medical Staff Bylaws, Rules and Regulations...Demonstrate and understanding and acceptance of my personal role in...accurate reporting of patient outcomes and clinical experience data..."

Review of the document titled 2017 Tennessee Department of Health Office of the State Chief Medical Examiner County Medical Examiner Handbook documented, "...Tennessee Code requires that any death which is suspicious, unusual or occurs under unnatural circumstances is to be reported to the county medical examiner. The mandatory reporters of such deaths are listed as "any physician, undertaker, law enforcement officer, or other person having knowledge of the death." T.C.A. § 38-7-108. Specifically, the county medical examiner of the county in which the death occurred is to be notified in all cases of:...Deaths in any suspicious/unusual/unnatural manner...The first decision point for the county medical examiner receiving a report of death occurring in a healthcare facility is to determine the probable manner of death. In cases of death in persons with a medical history of a disease process which could reasonably account for death and there is no non-natural process contributing in any way to the death, the physician treating the patient for that disease should complete and sign the death certificate...The manner of death [listed on the death certificate] represents the county medical

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 40	A 364		

examiner ' s opinion as to which category the death best fits into and is based on the circumstances surrounding the death...The five options for completion of the manner of death in Tennessee are Natural, Accident, Suicide, Homicide, and Could Not Be Determined...All deaths should be classified as to manner, and only one manner of death is to be chosen...Natural deaths are those due exclusively (100%) to disease and/or the aging process. A death in which a discrete, unnatural act contributes in any way towards the death, regardless of the interval elapsed between the event and demise, cannot be considered a natural death...Accident is defined as an unnatural death resulting from an inadvertent chance happening...The National Center for Health Statistics assigns ICD-10 codes to death certificates for vital statistics. As such, it is important to list each drug felt to be contributory to death on the death certificate [e.g., "acute combined drug toxicity (heroin, alprazolam, and ethanol)]" for improved data collection. Use of the terms "toxicity", "intoxication", "overdose", "ingested", "injected" or "inhaled" will be assigned a statistical code indicating that the event was non-natural...Standard Language for Cause of Death: Examples...Accidental...Acute drug/mixed drug (names of drug(s) intoxication...Standard Language for How Injury Occurred. These phrases should satisfy the purposes of item 34 on death certificate in the majority of non-natural deaths...injected prescription medications...38-7-108. Death under suspicious, unusual or unnatural circumstances. (a) Any physician, undertaker, law enforcement officer, or other person having knowledge of the death of any person from... deaths in any suspicious/unusual/unnatural manner, found

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 41 dead...shall immediately notify the county medical examiner or the district attorney general, the local police or the county sheriff, who in turn shall notify the county medical examiner. The notification shall be directed to the county medical examiner in the county in which the death occurred..." Review of the hospitals Disclosure of Unanticipated Outcomes policy documented, "... [Named Hospital System] clinicians share information with patients or their authorized representatives about their medical care, including information regarding unanticipated outcomes, whether arising as a result of pathologic process, complication of treatment or medical error...Unexpected Outcome - Unexpected change in patient's condition generally worse that what had been intended or hoped for, as a result of a...medical error....Medical Error - The failure of a planned action to be completed as intended...The Attending of Record has the ultimate responsibility for...Informing patients or their authorized representatives about unanticipated outcomes, including those associated with medical error...Discussions concerning sharing of unanticipated outcomes and/or medical errors are documented in patients' charts...Guidelines for Sharing Information about Unanticipated Outcomes ("Disclosure")...Documentation of disclosure in the medical record includes: Date, time, and place of disclosure; Names of those present; Nature of the discussion and areas covered; Offers of assistance, including bereavement support; Questions addressed in the discussion; Plan for continued communications..." Review of the hospital's Occurrence Reporting:	A 364		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 42 Patient and Visitor policy documented, "...When a serious or significant Event involving a patient or visitor occurs, immediately notify the Office of Risk and Insurance Management and the Administrative Coordinator...Event for the purposes of this policy is any of the following: Sentinel Event; Serious Reportable Event...Unanticipated outcome or occurrence involving a patient...Other terms which fall under the meaning of Event under this policy include...Medication Error, or adverse drug reaction...Medication Errors and Adverse Drug Events are the unintended, undesired, and unexpected effects of prescribed medications...or Medication Error requiring discontinuing a medication...supportive treatment, or resulting in temporary or permanent disability...a life threatening condition, death...Sentinel Event is a term established by The Joint Commission for an unexpected occurrence involving death...Serious Injury is unanticipated death...Serious Reportable Event is a term established by the National Quality Forum [NQF] that refers to 29 serious and largely preventable adverse Events..." Review of NQF's document titled Serious Reportable Events in Healthcare - 2011 Update... documented, "...Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)..." 2. Medical record review for Patient #1 revealed Physician #1 called the Medical Examiner (ME) to report Patient #1's death. There was no documentation in the record of the medication error being communicated to the ME per facility policy. There was no documentation in the	A 364		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 43	A 364		

medical record of the disclosure to the family documenting the Date, time, and place of disclosure; Names of those present; Nature of the discussion and areas covered; Offers of assistance, including bereavement support; Questions addressed in the discussion; or Plan for continued communications.

3. Interview with the Accreditation Regulatory Specialist (ARS) on 11/1/18 at 9:10 AM, in conference room 167, the ARS was setting up the computer to review Patient #1's medical record. There was a discussion regarding the death certificate and the manner of death. The ARS stated that you cannot make a medication administration accusation on the death certificate.

Telephone interview with Physician #1 on 11/2/18 at 9:56 AM, He/She was asked if he/she met with the family regarding Patient #1's event. He/She stated, "No, I did not. I met with [Named Physician #2]" Physician #1 was asked because he/she received a paralytic that directly contributed to his/her death, would you have marked "accidental" on the death certificate. Physician #1 stated, "I have always thought of accidents as...I have never marked that, but this does make sense with this case...".

Interview with the Senior Quality and Patient Advisor (SQPA) on 11/2/18 at 10:05 AM, (just after the above interview with Physician #1) he/she stated, "He/She [Physician #1] was led to say something 11 months later and I don't think that was accurate. We don't know, he/she [Patient #1] got such a small dose, and he/she was anxious about the test, so we can't say it contributed to his/her demise. Things can be disclosed after the fact [death]..."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 44	A 364		

There was no documentation in Patient #1's medical record how much Vecuronium he/she received, nothing in the medical record reflected he/she was declining. The medical record documented Patient #1 was improving, he/she was stable and was waiting for a floor bed.

Interview with Physician #2 on 11/2/18 at 11:24 AM, he/she was asked about the event surrounding Patient #1, and he/she stated, "I went down [to PET scan] when I heard it [Rapid Response] overhead. What was his/her clinical picture prior to the event? [He/She] had been stable and moved to stepdown. [His/Her] type of bleed was related to a suspected mass behind it." He/She was asked what he/she thought caused the event, and he/she stated, "Our leading cause was the medication error contributed to it, he/she became hypoxic...They had just completed CPR and he/she was intubated. After he/she was back in ICU, procedures were done..."
Physician #2 was asked if he/she talked to the family and were they told about the medication error, and Physician #2 stated, "Just the husband, I don't remember if they asked any questions."

Interview with Physician #3 on 11/2/18 at 1:15 PM, in conference room 167 , he/she confirmed he/she called the office of the Medical Examiner to report Patient #1's death. Physician #3 was asked if he/she informed the Medical Examiner that Patient #1 was given a paralytic drug by mistake that contributed to his/her death. Physician #3 stated that he/she could not remember. Physician #3 further stated that he/she answered the questions the Medical Examiner asked him/her but he/she could not remember the questions or the answers.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 364	Continued From page 45 Physician #3 was asked if he/she had any communication with the family regarding the event. Physician #3 stated that he/she talked to someone, distant relatives. He/She stated that he/she did not talk to the immediate family. Telephone interview with the Director of Investigations (DOI) in the Medical Examiners office on 11/5/18 at 10:01 AM, the DOI was asked about (Named Patient #1) and what was reported to them regarding Patient #1's death, and the DOI stated, "The date of death was 12/27/17 and was called in by [Named Physician #1]. The death certificate says he/she had a bleed. We declined jurisdiction because there was an MRI that confirmed the bleed..." The DOI was asked to describe the process when a physician reports a death, and the DOI stated, "We have a set of questions we ask such as admission, date and time of death, reason for the admission, what were they treated for." The DOI was given the information for Patient #1 and he/she looked up his/her case. The DOI was asked if administering a paralytic in error that caused a death would be something the Medical Examiner's office should be notified of, and the DOI stated, "Yes...The information shows he/she died of an Intracerebral bleed. We released jurisdiction because there was an MRI that confirmed the bleed. [Named Physician #1] stated maybe there was a medication error, but that was hearsay, nothing has been documented. Since there was no documentation and he/she said it was just hearsay, we didn't see any red flags..." The name of the drug was not disclosed to the ME.	A 364		
A 385	NURSING SERVICES CFR(s): 482.23	A 385		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 385	Continued From page 46 The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on policy review, document review, medical record review and interview, the hospital failed to ensure nursing services administered the correct medications, monitored the patient for any adverse reactions following the administration of a medication and prevented a preventable death. The failure of the hospital to mitigate risks associated with medication errors and ensure all patients' received the correct medications to protect their physical and emotional health and safety placed all patients in a SERIOUS and IMMEDIATE THREAT to the health and safety of all patients and placed them in IMMEDIATE JEOPARDY and risk of serious injuries and/or death. The findings included: 1. The hospital nursing services failed to ensure the correct medication was administered. Refer to A-0395	A 385		
A 395	RN SUPERVISION OF NURSING CARE CFR(s): 482.23(b)(3) A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on standards of practice, document	A 395		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 395	Continued From page 47	A 395		

review, review of hospital policies and procedures, medical record review, and interview, the hospital failed to ensure all Critical Care Registered Nurses (RN) implemented policies and procedures pertaining to the supervising and evaluating the nursing care that was provided for each patient for 1 of 1 (Patient #1) patients reviewed who received the wrong medication.

The failure of the hospital to ensure all nurses implemented standards of practice, policies and procedures pertaining to the supervision and evaluation of all patients resulted in a fatal medication error for Patient #1 and placed all patients in a SERIOUS and IMMEDIATE THREAT of their health and safety and placed them in IMMEDIATE JEOPARDY for risk of serious injuries and/or death.

The findings included:

1. Review of Lippincott Manual of Nursing Practice 10th Edition documented, "...Watch the patient's reaction to the drug during and after administration. Be alert for major adverse effects, such as...respiratory distress...NURSING ALERT...The nurse is ultimately accountable for the drug administered..."

Review of the hospital's High Alert Medications policy documented, "...High Alert Medications - Medications that bear a heightened risk of causing significant patient harm when used in error...Medication orders are reviewed by a pharmacist prior to removal from floor stock or an automated dispensing cabinet unless...A delay would harm the patient (including sudden changes in a patient's clinical status...Additional strategies are followed for a specified list of High

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 395	Continued From page 48	A 395		

Alert Medications...Higher level decision support...Independent Double-Check where electronic clinical systems prompt dual signoff..." Vecuronium was listed as a high alert medication. There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

The Drug Summary for Midazolam Hydrochloride (Versed). Retrieved from PDR, 2018, http://www.pdr.net documented, "...CLASSES Anxiolytics Benzodiazepine Sedative/Hypnotics Other General Anesthetics...Administration of midazolam requires an experienced clinician trained in the use of resuscitative equipment and skilled in airway management...Monitor patients for early signs of respiratory insufficiency, respiratory depression, hypoventilation, airway obstruction, or apnea (i.e., via pulse oximetry), which may lead to hypoxia and/or cardiac arrest.

The facility's "High Alert Medications Chart: Adult Patients Revised May 2018" did not list any moderate sedation agents such as Versed.

Review of the hospital's Medication Administration documented, "[Named Hospital] staff validate the five rights of medication administration to minimize medication errors...Right patient; Right medication; Right dose; Right route...Right time to adhere to the prescribed frequency and time of administration...Document medication administration in the electronic medical record to include, at a minimum, the following...Date and time of administration; Medication name and strength; Dosage of medication administered...Route of administration..."

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 395	Continued From page 49	A 395		

There was no documentation in this policy detailing any procedure or guidance regarding the manner and frequency of monitoring patients during and after medications were administered.

There was no documentation in Patient #1's medical record that Vecuronium or Versed was administered to her on 12/26/17.

Review of the hospital's RN 2CC Job Description documented, "...CORE COMPETENCIES...Fulfills Safety and Regulatory Requirements: Understands all aspects of providing a safe environment and performs routine safety checks to prevent safety hazards from occurring..."

2. Medical record review for Patient #1 revealed the patient was admitted to the hospital on 12/24/17 with diagnoses of Intraparenchymal Hematoma of the Brain, Headache, Homonymous Hemianopia (vision field loss of both eyes)-Left, Atrial Fibrillation, and Hypertension.

A physician progress note written on 12/25/17 at 1:32 PM, by Physician #2 documented, "...no acute events since admission...encourage out of bed activity...DISPO [Disposition] no further critical care issues. likely going to the floor today..."

Review of medication order #60651186 order details dated 12/16/17 at 3:00 PM revealed Versed 2 milligrams (mgs) intravenous one time. Administration instructions documented, "For PET scan if first milligram insufficient, can give 1-2mg additional if needed..."
Review of the Automatic Dispensing Cabinet

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VANDERBILT UNIVERSITY MEDICAL CENTER	1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232

(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) COMPLETION DATE
A 395	Continued From page 50	A 395		

(ADC) detail report revealed the order was entered on 12/26/18 2:47 PM. Pharmacy verified the order at 2:49 PM. Versed was not removed from the Automated Dispensing Cabinet (ADC).

Review of the ADC detail report dated 12/26/17 revealed Vecuronium (a neuromuscular paralytic drug) 10 mg. injection vial was taken by RN #1 at 2:59 PM from the ADC located in the Neuro ICU using the override feature. There was no physician order for Patient #1 to receive this drug. The override was not verified by Pharmacy.

Interview with the Nurse Manager of Neuro Unit on 11/1/18 at 12:36 PM in conference room 167 the Nurse Manager was asked if there was documentation anywhere in Patient #1's medical record that he/she received Vecuronium and how much and when he/she received it. The Nurse Manager stated, "No..."

A physician progress note written on 12/26/17 at 6:28 PM by an Advance Practice Registered Nurse (APRN) and co-signed by Physician #2 documented, "...Received patient to NCU [Neuro Critical Care Unit] after cardiac arrest in PET scan. Per report, ROSC [Return of Spontaneous Circulation] received after approximately 2 rounds of ACLS [Advanced Cardiac Life Support]. Patient was intubated during event...Current Facility-Administered Medications...Vecuronium..." No dose, route or frequency was documented.

A physician progress note written on 12/26/17 at 6:36 PM, by Physician #2 documented, "...After a couple of hours in the ICU, [he/she] began displaying myoclonic jerks w/stimulus interspersed with posturing...pt's neuro exam is

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	440039	A. BUILDING _____ B. WING _____	C 11/08/2018

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A 395	Continued From page 51 very concerning. after d/w [discussion with] neurology team, they suspect that [his/her] exam is c/w [consistent with] what would be seen after anoxic brain injury - CT [Computerized Tomography] head showed some increase in swelling, but area of bleed not worsened - initially suspected worsening hemorrhage as reason for arrest, however after further discussion, it is suspected that [he/she] may have received an incorrect medication which contributed to the event...DISPO: pt's course is very concerning. Given myoclonic jerks there is high concern for anoxic brain injury..." A physician progress note written on 12/27/17 at 12:27 AM, by a physician and cosigned by Physician #2 documented, "...I discussed the case with the neurology team and it is felt that these changes in exam likely represent progression towards but not complete brain death...[He/She] was made a DNR/DNI [Do Not Resuscitate/Do Not Intubate]. Palliative extubation was performed 12/27/17 at 12:57 AM. Vasoactive infusions were then discontinued. Time of cardiopulmonary death was 1:07 AM by pulselessness on [his/her] arterial line..." Interview with the Manager of the Adult Patient Safety Team (MAPST) on 10/31/18 beginning at 3:15 PM, in conference room 167, the MAPST was asked about his/her role regarding [Named Patient #1]. The MAPST stated, "...We learned the nurse and [his/her] Orientee were called to Radiology for a patient that was having some anxiety...[He/She] [RN #1] pulled the med from ICU. [He/She] went into the system and picked the patient and typed "VE" for Versed and did a search. [He/She] chose Vecuronium because it was the first that came up. The window popped	A 395		

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A 395	Continued From page 52	A 395		

and alert up notifying that drug was not in the patient's profile and [He/She] over rode that, which can be done due to possible emergencies. This drug was a powder and had to be reconstituted, Versed did not [have to be reconstituted]. Reconstitution was a question of where was it done. [He/She] gives the drug to the patient and left the patient unattended." The MAPST was asked how long was Patient #1 left unattended. The MAPST stated, "They found [him/her] in arrest, called the code. I don't know how long it was between when the med was given and the code was called..."

Telephone interview with RN #1 on 11/5/18 beginning at 4:41 PM, RN #1 was asked to describe the circumstances leading up to Patient #1's death beginning on Tuesday 12/26/17. RN #1 stated, "I was in a patient care role, I was the help-all nurse. A help-all nurse is a resource nurse and I had an Orientee"
RN #1 stated that RN #2 had asked (him/her) to go downstairs to Radiology PET scan and administer the medication Versed to Patient #1 because the patient was not able to tolerate the PET scan procedure or they would have to send him/her back and reschedule it.
RN #1 stated he/she searched for the Versed under Patient #1's profile in the ADC and RN #1 couldn't find it. RN#1 stated that he/she then chose the override setting on the ADC and searched for the Versed.
RN #1 stated he/she was talking to the Orientee while he/she was searching the ADC for the Versed and had typed in the first 2 letters of Versed which are VE and chose the 1st medication on the list.
RN #1 stated he/she took the medication vial out of the ADC, and looked at the back of the vial at

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A 395	Continued From page 53	A 395		

the directions for how much to reconstitute it with.
RN #1 verified he/she did not re-check the name on the vial.
RN #1 stated he/she grabbed a sticker from the patient's file, a handful of flushes, alcohol swabs, a blunt tip needle. RN #1 stated he/she put the medication vial in a baggie and wrote on the baggie, "PET scan, Versed 1-2 mg" and went to Radiology to administer the medication to Patient #1.
RN #1 was asked how long it took him/her to get to the Radiology department PET scan, and RN #1 stated, "5 minutes or less, it was my first time to go to PET scan, I had to ask for directions".
RN #1 stated, "I saw one patient [who was Patient #1] on one of our beds, I checked the patient for [his/her] identity, and told [him/her] I was there to give [him/her] something to help [him/her] relax".
RN #1 stated, "I reconstituted the medication and measured the amount I needed"
The RN stated Radiology Technician #1 was there at the time he/she (RN #1) administered the medication IV to Patient #1. RN #1 stated he/she left the Radiology PET scan area after he/she had administered the medication to Patient #1.
RN #1 was asked how much medication did he/she administer to Patient #1, and the RN stated, "I can't remember, I am pretty sure I gave [him/her] 1 milliliter.
RN #1 was asked what was done with any left over medication, and the RN stated, "I put the left over in the baggie and gave it to [Named RN #2]..."
RN #1 was asked what he/she did after administering the medication to Patient #1, and the RN stated he/she left Patient #1 in Radiology.
RN #1 confirmed that he/she did not monitor Patient #1 after the medication was administered.

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A 395	Continued From page 54	A 395		

RN #1 was asked what happened next and the RN stated, "Patient #1's family was standing outside in the hallway...we heard a rapid response call for PET scan. That was a red flag since the patient was ours, so [Named RN #2] called down there [to the PET scan] but there was no answer. The family looked at us and said "ours?" [Named RN #2] said "we are going to make sure." We tried to call PET scan again, we were being responsible to go to see if it was our patient".

RN #1 stated that he/she and RN #2 went to PET scan and when they arrived Patient #1 was intubated and had regained a heart rate. The RN stated he/she, Physician #2, and the Charge Nurse moved Patient #1 back to the ICU.

RN #1 stated, "I told [Named Physician #2] that I had given him/her Versed a few minutes ago...I reminded the Nurse Practitioner that Patient #1 was awake but unmonitored when I gave him/her the Versed".

RN #1 stated RN #2 approached him/her and asked, "Is this the med you gave [him/her]?" and RN #1 responded "yes". RN #1 then stated RN #2 said, "This isn't Versed, It's Vecuronium."

RN #1 stated he/she then went into Patient #1's room and informed Physician #2, and the NP that he/she had made a mistake and administered Vecuronium to Patient #1 instead of Versed.

RN #1 was asked if he/she documented he/she had administered the Vecuronium in Patient #1's medical record. RN #1 stated, "I did not. I spoke with [Named Nurse Manager] and he/she told me the new system would capture it on the MAR [Medication Administration Record]. I asked and he/she said it would show up in a special area in a different color."

RN #1 was asked if he/she could remember how much Vecuronium he/she administered to Patient

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A 395	Continued From page 55 #1, and RN #1 stated, "I would have given her 1 milligram." RN #1 was asked if he/she talked to anyone at the hospital in the days after the event, and the RN stated, "I did have some conversations with risk management. I don't remember all I said. It was on the phone. I came back on the 3rd [January] and saw [Named Nurse Manager]. That is when I was terminated. They sent me to an employee resource counsellor for my own personal wellbeing." RN #1 was asked about the "help-all nurse" role and was there documentation of what was done while working a shift, and the RN stated, "If you do something, you just chart it for that patient". The RN stated there was not an actual job description for the role of a "help-all nurse" Refer to A 144 and A145.	A 395		