

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 11/16/2018
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440039	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 11/08/2018
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NAME OF PROVIDER OR SUPPLIER VANDERBILT UNIVERSITY MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 1211 MEDICAL CENTER DRIVE NASHVILLE, TN 37232
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A 000	<p>INITIAL COMMENTS</p> <p>An unannounced onsite survey was conducted 10/31/18 to 11/8/18 to investigate complaint # TN00045852.</p> <p>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.</p> <p>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.</p>	A 000	Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the Hospital of the truth of the facts alleged or conclusions set forth in this statement of deficiencies. The Plan of Correction is prepared and/or executed because it is required by the provisions of federal law. Vanderbilt University Medical Center ("the Hospital"), its governing body, its administrative team, and its Medical Staff are committed to complying with federal and state law, while providing quality health care services to patients in a safe setting. The Hospital has taken the corrective measures outlined in this Plan of Correction to address the cited deficiencies outlined in the Form CMS-2567.	
A 115	<p>PATIENT RIGHTS CFR(s): 482.13</p> <p>A hospital must protect and promote each patient's rights.</p> <p>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.</p> <p>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</p>	A 115	<p>Immediately following the survey, the Hospital reviewed existing policies and procedures to determine whether revisions and/or new policies were required. Although numerous policies are in place to meet the requirements of 42 CFR §482.13 and address the cited deficiency, the Hospital made updates to select policies and procedures applicable to medication administration. The updates to policies and procedures are also discussed in detail in response to Tags A 144 and A 145, below.</p> <p>The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes:</p>	12/3/18

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

TITLE

(X6) DATE

C. Wright Poirier

CEO

11/26/18

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

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A 115	<p>Continued From page 1</p> <p>IMMEDIATE JEOPARDY and risk of serious injuries and/or death.</p> <p>The findings included:</p> <p>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.</p> <p>Refer to A-0144</p> <p>2. The hospital failed to ensure patients were free from neglect. Refer to A-0145</p>	A 115	<ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond critically ill patients. As such, the newly amended policy is titled "Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy 	11/27/18
A 144	<p>PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2)</p> <p>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.</p> <p>The failure of the hospital to ensure all nurses followed medication administration policies 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</p>			

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A 144	<p>Continued From page 2</p> <p>safety and placed them in IMMEDIATE JEOPARDY for risk of serious injuries and/or death.</p> <p>The findings included:</p> <p>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..."</p> <p>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..."</p> <p>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.</p> <p>Review of the document ISMP List of High-Alert Medications in Acute Care Settings...ISMP 2018</p>	A 115	<p>states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the monitoring to be based on the patient's condition, type of medication, and route. Documentation will be in accordance with VUMC's Medication Administration Policy. The Transport Policy further states that such monitoring may include, but is not limited to, direct observation, vital signs, and neuro checks. The revised Transport Policy further requires appropriate documentation to be completed in the patient's medical record upon leaving and returning to the unit, including the times the patient leaves and returns to the unit.</p> <ul style="list-style-type: none"> The Hospital has revised its High Alert Medication Policy, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving administration of high alert medications. Specifically, the amended High Alert Medication Policy states that the patient's clinical status is monitored to evaluate patient response to 	11/27/18

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A 144	<p>Continued From page 3</p> <p>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)..."</p> <p>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..."</p> <p>Review of document titled Joint Commission eyes overrides of dispensing cabinets dated May, 2018</p>	A 115	<p>medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neurological status.</p> <ul style="list-style-type: none"> The Hospital's Medication Administration Policy has been revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration. 	11/27/18

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A 144	<p>Continued From page 4</p> <p>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"..."</p> <p>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..."</p> <p>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,</p>	A 115	<ul style="list-style-type: none"> The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The Hospital determined that it has in place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no updates to the SOP for Moderate Sedation are required. <u>Training</u>: By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), 	12/3/18

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A 144	<p>Continued From page 5</p> <p>respiratory depression, hypoventilation, airway obstruction, or apnea (i.e., via pulse oximetry), which may lead to hypoxia and/or cardiac arrest.</p> <p>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..."</p> <p>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.</p> <p>2. Medical record review for Patient #1 revealed the patient was admitted to the hospital on</p>	A 115	<p>respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the Transport Policy, High Alert Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide regular updates to directors of these departments to ensure compliance.</p> <ul style="list-style-type: none"> • <u>Monitoring</u>: Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the 	12/3/18

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A 144	<p>Continued From page 6</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	A 115	<p>appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non-compliance, inconsistencies or questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee.</p> <p>The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes:</p> <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC 	

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A 144	<p>Continued From page 7</p> <p>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.</p> <p>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".</p> <p>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..."</p> <p>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.</p> <p>3. Telephone interview with (b)(6) on 11/5/18 beginning at 4:41 PM, (b)(6) was asked to describe the circumstances leading up to Patient #1's death beginning on Tuesday 12/26/17. RN</p>	A 115	<p>Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the override list, based on the work group's determination that the clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by 	11/27/18

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A 144	<p>Continued From page 8</p> <p>#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"</p> <p>(b)(6) 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.</p> <p>(b)(6) 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.</p> <p>(b)(6) 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.</p> <p>(b)(6) 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. (b)(6) verified he/she did not re-check the name on the vial.</p> <p>(b)(6) stated he/she grabbed a sticker from the patient's file, a handful of flushes, alcohol swabs, a blunt tip needle. (b)(6) 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.</p> <p>(b)(6) was asked how long it took her to get to the Radiology department PET scan, and (b)(6) stated, "5 minutes or less, it was my first time to go to PET scan, I had to ask for directions". (b)(6)</p> <p>(b)(6) 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".</p>	A 115	<p>the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the first two letters of "Paralyzing Agent" - which will then pull up the list of Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be effective in both eStar and AcuDose as of November 27, 2018. Effective on November 27, 2018, this updated procedure is documented by an amendment to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients, which are incorporated into the High Alert Medications Policy. These charts have been amended to list the four (4) specific Paralyzing Agents available at the Hospital, and to reflect the updated nomenclature of "Paralyzing Agent [medication name]".</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement warning in AcuDose 	11/27/18

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A 144	<p>Continued From page 9</p> <p>(b)(6) stated, "I reconstituted the medication and measured the amount I needed"</p> <p>The RN stated Radiology Technician #1 was there at the time he/she administered the medication IV to Patient #1. (b)(6) 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 (b)(6) stated, "I can't remember, I am pretty sure I gave [him/her] 1 milliliter.</p> <p>(b)(6) 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]..."</p> <p>(b)(6) was asked what he/she did after administering the medication to Patient #1, and the RN stated he/she left Patient #1 in Radiology.</p> <p>(b)(6) confirmed that he/she did not monitor Patient #1 after the medication was administered.</p> <p>(b)(6) 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".</p> <p>(b)(6) 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 (b)(6) stated he/she, Physician #2, and the Charge Nurse moved Patient #1 back to the ICU.</p> <p>(b)(6) stated, "I told [Named Physician #2] that I had given [Patient #1] Versed a few minutes ago...I reminded the Nurse Practitioner that</p>	A 115	<p>and eStar, stating: "WARNING: PARALYZING AGENT - Causes Respiratory Arrest – Patient Must Be Ventilated." The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, effective on November 27, 2018, to specify this pop-up warning as a Specific Safety Strategy for PARALYZING AGENTS.</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement new procedures for shrink wrap packaging to be added to all vials of Paralyzing Agents dispensed in AcuDose throughout the Hospital, and effective November 27, 2018 amendments to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients will be approved to specify a Specific Safety Strategy that all Paralyzing Agents dispensed in AcuDose cabinets throughout the Hospital will have shrink wrap packaging. The Hospital Executive Pharmacy Leadership will monitor compliance with the required shrink wrap packaging of Paralytic Agents by conducting random audits of all AcuDose cabinets throughout the hospital and validating packaging compliance for a minimum of three 	11/27/18

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A 144	<p>Continued From page 10</p> <p>Patient #1 was awake but unmonitored when I gave the Versed".</p> <p>RN #1 stated RN #2 approached him/her and asked, "Is this the med you gave [named Patient #1]?" and (b)(6) responded "yes". (b)(6) then stated RN #2 said, "This isn't Versed, it's Vecuronium."</p> <p>(b)(6) 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.</p> <p>(b)(6) was asked if it was documented he/she had administered the Vecuronium in Patient #1's medical record. (b)(6) 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."</p> <p>(b)(6) was asked if he/she could remember how much Vecuronium she administered to Patient #1, and (b)(6) stated, "I would have given 1 milligram."</p> <p>(b)(6) 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."</p> <p>(b)(6) was asked about the "help-all nurse" role and was there documentation of what was done while working a shift, and the (b)(6) stated, "If you do something, you just chart it for that patient". The (b)(6) stated there was not an actual job description for the role of a "help-all nurse"</p>	A 115	<p>months of consecutive 100% compliance.</p> <ul style="list-style-type: none"> As of November 27, 2018, the Hospital will finalize and implement new procedures to require the additional Specific Safety Strategy for all Paralyzing Agents to include an Independent Double Check conducted by two licensed registered nurses prior to the administration of a Paralyzing Agent, where electronic clinical systems prompt dual sign off for bolus doses and upon the following for infusions: <ul style="list-style-type: none"> Initiation of infusion Change of container Handover <p>The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, which revisions are scheduled to be approved on November 27, 2018, to specify the Specific Safety Strategy that all Paralyzing Agents require such Independent Double Check.</p> <p><u>Training:</u> By November 26, 2018, every nurse and paramedic who work in an area of the Hospital where Paralyzing Agents are available in AcuDose dispensing cabinets, are required to complete an online training module outlining</p>	<p>11/27/18</p> <p>11/26/18</p>

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A 144	<p>Continued From page 11</p> <p>4. Interview with (b)(6) (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..."</p> <p>Telephone interview on 11/5/18 at 9:29 AM with (b)(6) (Patient #1's primary care nurse prior to the Event) the (b)(6) was asked to describe the events surrounding Patient #1's death. (b)(6) 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</p>	A 115	<p>the process changes, Independent Double Check, vial packaging and naming convention changes. Any nurse or paramedic staff member required to complete such training, and who has not completed the computer-based training prior to November 27, 2018 for any reason, including being on vacation or not scheduled to work at the Hospital during the time period, will not be permitted to begin their next shift at the Hospital without first completing the required training. The Hospital is monitoring the completion of the required training programs, and as of November 21, 2018, 1,334 individuals, which is 53% percent of the Hospital's staff members required to receive the education, had completed the training requirement.</p> <ul style="list-style-type: none"> <u>Monitoring</u>: The Hospital will implement several measures to monitor compliance with the updated medication administration requirements. Beginning on November 27, 2018, the Hospital's Enterprise Medication Safety Officer, in collaboration with the Chief Nursing Officers, Executive Pharmacy Leadership, and Chief of Staff, will compile monthly reports of overrides from AcuDose cabinets for 	11/27/18

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A 144	<p>Continued From page 12 involvement."</p> <p>(b)(6) was asked how long he had the bag with the vial in it before he/she realized it was the wrong medication. (b)(6) stated, "It was less than 15 minutes..."</p> <p>Telephone interview with (b)(6) 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 (b)(6) 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..."</p>	A 115	<p>paralyzing agents, which will be reviewed at the medication safety committee, as well as on the unit level, and assessed for appropriateness. Such monthly reporting will be ongoing, and continue for three months following November 27, 2018. Thereafter, the Enterprise Medication Safety Officer will continue to periodically review and provide override performance reports as part of ongoing medication safety committee work.</p> <p>In addition, beginning on November 27, 2018 and continuing on a monthly basis until 100% compliance is achieved, Hospital's Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p>		

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A 144	Continued From page 13 (b)(6) was asked about how long Patient #1 was in the room after the nurse came and administered the medication, and (b)(6) 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]" (b)(6) was asked if Patient #1 was monitored after receiving the medication for anxiety, and (b)(6) stated that the RN #1 did not stay and monitor the patient after he/she administered the medication.	A 115	In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the preparation of drugs and safe medication practices. All nurse residents, who are new graduate registered nurses hired with less than six months of nursing experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.	
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		<ul style="list-style-type: none"> Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a 	

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A 145	<p>Continued From page 14</p> <p>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.</p> <p>The findings included:</p> <p>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..."</p> <p>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)..."</p> <p>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.</p>	A 115	<p>mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and based on the issues revealed in results of the audits described herein.</p> <p>The Hospital has reviewed its policies and procedures related the role of the "Help All Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care 	11/20/18

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A 145	<p>Continued From page 15</p> <p>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..."</p> <p>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.</p> <p>Review of the facility's "Medication Administration" documented, "[Named Hospital] staff validate the five rights of medication</p>	A 115	<p>units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of Care document on an annual basis to ensure duties of the position remain complete and accurate.</p> <p>The Hospital has reviewed its policies and procedures related to state reporting, and has made the following changes:</p> <ul style="list-style-type: none"> The Hospital reviewed its Occurrence Reporting: Patient and Visitor policy, which outlines requirements of every Hospital employee, attending physician and house staff member to report certain occurrences to the Hospital's Office of Risk and Insurance Management, either through the online occurrence reporting system or through a phone call to Risk Management. The Hospital has revised the Occurrence Reporting: Patient and Visitor policy to require Risk Management to report any a) incidents of abuse, neglect, or misappropriation reported to the Hospital department as complaints for certification processes; b) strike by staff; c) 	11/27/18

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A 145	<p>Continued From page 16</p> <p>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..."</p> <p>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.</p> <p>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..."</p> <p>4. Review of State Operations Manual, Appendix A Survey Protocol, Regulations, and Interpretive 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</p>	A 115	<p>external disaster impacting a Hospital facility; d) disruption of any service vital to the continued safe operation of the Hospital facility, or to the health and safety of its patients and personnel; and e) fires at a Hospital facility that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires. These policy revisions are scheduled to be approved by Executive Policy Committee of the Medical Center Medical Board effective November 27, 2018. The Occurrence Reporting: Patient and Visitor policy places the responsibility for reporting to the Tennessee Department of Health pursuant to the Health Data Reporting Act of 2002 with the Office of Risk and Insurance Management.</p> <p>Effective on November 27, 2018, the Hospital will implement a revised procedure during the established weekly meeting of the Event Review Committee to include regular evaluations of whether occurrences reported to the Office of Risk and Insurance Management require a report to the Tennessee Department of Health, pursuant to state law</p>	11/27/18	

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A 145	<p>Continued From page 17</p> <p>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..."</p> <p>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..."</p> <p>5. The "Tennessee Code Annotated Title 71...Chapter 6...Part 1..." documented, "...71-6-103...Any person, including, but not limited to, a physician, 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</p>	A 115	<p>requirements. The Event Review Committee reviews patient events with harm or potential harm on a weekly basis, to identify those events which may require an Event Analysis pursuant to the Hospital policies, further investigation by Risk and Insurance Management, external reporting, or other potential safety or risk issues. The Event Review Committee is a Quality Improvement Committee (QIC) as defined pursuant to TCA §§ 63-1-150 and 68-11-272 and is comprised of representatives from Risk and Insurance Management; Quality, Safety, and Risk Prevention; and Patient Safety Officers. The Event Review Committee reports to the Self Insurance Trust, which reports to the Hospital Medical Center Medical Board. The participants of the Event Review Committee have been informed of the changes to the Occurrence Reporting policy and these additional procedures. The Senior Vice President of Quality, Safety and Risk Prevention and the Vice President of Risk and Insurance Management will continue participate in such weekly committee meetings and will monitor state reporting processes to ensure the Hospital reports as required by state and federal law. Further, the</p>	

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A 145	<p>Continued From page 18</p> <p>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..."</p> <p>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..."</p> <p>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.</p> <p>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</p>	A 115	<p>Hospital is currently communicating with the Tennessee Department of Health regarding additional guidance on reportable events under state law.</p> <ul style="list-style-type: none"> The Hospital has reviewed its policy outlining reporting requirements to the Davidson County Medical Examiner, including its Deaths Requiring Reporting to the Medical Examiner policy (hereinafter, "Medical Examiner Policy"). The Hospital has amended the Medical Examiner Policy, which amendments are scheduled to be approved on November 27, 2018, to clarify that all details supporting a decision of: a) a suspicious, unusual or unnatural death, including unexplained surgical and anesthetic deaths, and b) death during or as a result of a diagnostic or therapeutic procedure, medication error, or adverse, allergic, or toxic reaction to a therapeutic agent, shall be reported to the Medical Examiner. The revised Medical Examiner Policy also requires all conversations with the Medical Examiner's Office to be documented in the patient's medical record, including the rationale for reporting pursuant to the criteria outlined in the Policy. 	11/27/18

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A 145	<p>Continued From page 19</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>Review of the time line for the medication error event that occurred on 12/26/17 revealed the following:</p>	A 115	<ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring every Attending Physician and House Staff to complete education regarding the revised Medical Examiner Policy requirements, reporting requirements under state law, and documentation in the medical record under the Policy, as well as documenting communications and disclosure with family and/or patient representative. <u>Monitoring</u>: The Chief of Staff, Office of Decedent Affairs and Quality, Safety and Risk Prevention will review Medical Examiner reporting to ensure the Hospital reports as required by state law. Additionally, this group will conduct audits of a designated number of patients who died under circumstances potentially reportable under the Medical Examiner Policy, randomly selected, in order to assess compliance with state reporting requirements. In the event such an audit reveals non-compliance, inconsistencies or questions, the Office of Decedent Affairs will elevate these issues to the VUMC Quality Steering Committee to determine whether additional steps are required for compliance, such as targeted education and/or training. 	12/3/18

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A 145	<p>Continued From page 20</p> <p>Patient #1 was scheduled for a PET scan at 2:00 PM.</p> <p>No documentation when Patient #1 arrived in Radiology.</p> <p>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)</p> <p>An override pull for Vecuronium was documented at 2:59 PM.</p> <p>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.</p> <p>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.</p> <p>Interview with the (b)(6) and the (b)(6) 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."</p> <p>Interview with the (b)(6) on 10/31/18 at 3:02 PM, the (b)(6) 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</p>	A 144	<p>The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond critically ill patients. As such, the newly amended policy is titled "Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical 	11/27/18	

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A 145	<p>Continued From page 21 [regulations], page 31, 6d."</p> <p>Interview with the (b)(6) on 11/1/18 at 4:23 PM, the (b)(6) 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..."</p> <p>Telephone interview with (b)(6) (Patient #1's primary care nurse prior to the Event) on 11/5/18 beginning at 9:29 AM. (b)(6) was asked to describe the events surrounding [Named Patient #1's] death. (b)(6) 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</p>	A 144	<p>record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the monitoring to be based on the patient's condition, type of medication, and route. Documentation will be in accordance with VUMC's Medication Administration Policy. The Transport Policy further states that such monitoring may include, but is not limited to, direct observation, vital signs, and neuro checks. The revised Transport Policy further requires appropriate documentation to be completed in the patient's medical record upon leaving and returning to the unit, including the times the patient leaves and returns to the unit.</p> <ul style="list-style-type: none"> The Hospital has revised its High Alert Medication Policy, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving administration of high alert 	11/27/18

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A 145	<p>Continued From page 22 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..."</p> <p>Telephone interview with the (b)(6) (b)(6) at the Medical Examiner's Office on 11/5/18 at 10:01 AM, the (b)(6) was asked about (Named Patient #1) and what was reported to them regarding [Patient #1's] death. The (b)(6) 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..."</p> <p>Telephone interview with (b)(6) on 11/5/18 beginning at 4:41 PM, (b)(6) 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</p>	A 144	<p>medications. Specifically, the amended High Alert Medication Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neurological status.</p> <ul style="list-style-type: none"> The Hospital's Medication Administration Policy has been revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication 	11/27/18

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A 145	Continued From page 23 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 our 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	A 144	Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration. <ul style="list-style-type: none"> The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The Hospital determined that it has in place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no 	

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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." (b)(6) was asked if he/she documented the Vecuronium in Patient #1's medical record. (b)(6) 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]. (b)(6) stated that he/she left Patient #1 in Radiology. (b)(6) confirmed that he/she did not monitor Patient #1 after the medication was administered.	A 144	updates to the SOP for Moderate Sedation are required. • <u>Training</u> : By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the Transport Policy, High Alert Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3 rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide regular updates to directors of these departments to ensure compliance.	12/3/18
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		• <u>Monitoring</u> : Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will	12/3/18

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A 286	<p>Continued From page 25</p> <p>administrative officials are responsible and accountable for ensuring the following: ...</p> <p>(3) That clear expectations for safety are established.</p> <p>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.</p> <p>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.</p> <p>The findings included:</p> <p>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.</p>	A 144	<p>oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non-compliance, inconsistencies or questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee.</p> <p>The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes:</p> <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning 	

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A 286	<p>Continued From page 26</p> <p>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.</p> <p>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)..."</p> <p>The hospital's document titled High Alert Medications Chart: Adult Patients Revised May 2018 did not list any moderate sedation agents such as Versed.</p> <p>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</p>	A 144	<p>on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the override list, based on the work group's determination that the clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. 	11/27/18

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A 286	<p>Continued From page 27</p> <p>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..."</p> <p>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!"..."</p> <p>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..."</p>	A 144	<p>The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the first two letters of "Paralyzing Agent" - which will then pull up the list of Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be effective in both eStar and AcuDose as of November 27, 2018. Effective on November 27, 2018, this updated procedure is documented by an amendment to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients, which are incorporated into the High Alert Medications Policy. These charts have been amended to</p>	

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A 286	<p>Continued From page 29</p> <p>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."</p> <p>The (b)(6) was asked how long was [the patient] was left unattended, and the (b)(6) 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 (b)(6) was asked if any education was done for the nursing staff. The (b)(6) 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'.</p> <p>Interview with the (b)(6) on 10/31/18 at 3:30 PM, in conference room 167, the (b)(6) was asked if there was any discussion at any meeting after the event occurred in December, 2017. As the (b)(6) reviewed the minutes for each monthly meeting Med Executive Meeting from January through October 2018, the (b)(6) 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</p>	A 144	<p>Pharmacy Leadership will monitor compliance with the required shrink wrap packaging of Paralytic Agents by conducting random audits of all AcuDose cabinets throughout the hospital and validating packaging compliance for a minimum of three months of consecutive 100% compliance.</p> <ul style="list-style-type: none"> As of November 27, 2018, the Hospital will finalize and implement new procedures to require the additional Specific Safety Strategy for all Paralyzing Agents to include an Independent Double Check conducted by two licensed registered nurses prior to the administration of a Paralyzing Agent, where electronic clinical systems prompt dual sign off for bolus doses and upon the following for infusions: <ul style="list-style-type: none"> Initiation of infusion Change of container Handover <p>The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, which revisions are scheduled to be approved on November 27, 2018, to specify the Specific Safety Strategy that all Paralyzing Agents require such Independent Double Check.</p>	<p>11/27/18</p> <p>11/27/18</p>

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A 286	<p>Continued From page 31</p> <p>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]."</p> <p>Interview with the (b)(6) on 11/1/18 at 4:23 PM, the (b)(6) 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</p>	A 144	<p>November 27, 2018, the Hospital's Enterprise Medication Safety Officer, in collaboration with the Chief Nursing Officers, Executive Pharmacy Leadership, and Chief of Staff, will compile monthly reports of overrides from AcuDose cabinets for paralyzing agents, which will be reviewed at the medication safety committee, as well as on the unit level, and assessed for appropriateness. Such monthly reporting will be ongoing, and continue for three months following November 27, 2018. Thereafter, the Enterprise Medication Safety Officer will continue to periodically review and provide override performance reports as part of ongoing medication safety committee work.</p> <p>In addition, beginning on November 27, 2018 and continuing on a monthly basis until 100% compliance is achieved, Hospital's Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and</p>	11/27/18

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A 286	<p>Continued From page 32</p> <p>[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..."</p> <p>Interview with (b)(6) 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</p>	A 144	<p>the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p> <p>In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the preparation of drugs and safe medication practices. All nurse residents, who are new graduate registered nurses hired with less than six months of nursing experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.</p> <ul style="list-style-type: none"> • Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a 	

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A 286	<p>Continued From page 33 information to her reports..."</p> <p>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 (b)(6) 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."</p> <p>4. Interview with the (b)(6) (b)(6) 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</p>	A 144	<p>variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and based on the issues revealed in results of the audits described herein.</p> <p>The Hospital has reviewed its policies and procedures related the role of the "Help All Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical 	11/20/18

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A 286	Continued From page 34 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	A 144	Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of Care document on an annual basis to ensure duties of the position remain complete and accurate.	
		A 145	The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes: <ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond critically ill patients. As such, the newly amended policy is titled 	11/27/18

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A 286	<p>Continued From page 35</p> <p>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.</p> <p>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.</p> <p>5. Interview with the (b)(6) on 11/6/18 at 12:57 PM, in conference room 167, he/she was asked what is the process for incidents, and the (b)(6) 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 look and take immediate action on all events. He was asked why Rocuronium is still available in the Acudose for override, and the (b)(6) 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 (b)(6) stated, "Let's get the pharmacist in here to answer that...EA is considered a QAPI"</p> <p>Interview with the (b)(6) (b)(6) #2, and the (b)(6) 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 (b)(6) (b)(6) stated, "We felt we had appropriate</p>	A 145	<p>"Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the monitoring to be based on the patient's condition, type of</p>	

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A 286	<p>Continued From page 36</p> <p>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."</p> <p>The (b)(6) 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."</p> <p>The (b)(6) 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."</p> <p>The (b)(6) stated, "The number of safety points this nurse went through was numerous." The (b)(6) was asked why was there a delay in nursing education.</p> <p>The (b)(6) 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."</p> <p>The (b)(6) 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.</p> <p>The (b)(6) stated, "I have never heard that term, that is not a [Named Hospital] wide term. But believe me, we are going to look at it."</p> <p>The (b)(6) was asked about the process for QAPI and where does the analysis begin and does it get to the system level for review.</p> <p>The (b)(6) stated that each hospital [Adult,</p>	A 145	<p>medication, and route.</p> <p>Documentation will be in accordance with VUMC's Medication Administration Policy. The Transport Policy further states that such monitoring may include, but is not limited to, direct observation, vital signs, and neuro checks. The revised Transport Policy further requires appropriate documentation to be completed in the patient's medical record upon leaving and returning to the unit, including the times the patient leaves and returns to the unit.</p> <ul style="list-style-type: none"> The Hospital has revised its High Alert Medication Policy, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving administration of high alert medications. Specifically, the amended High Alert Medication Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct 	11/27/18

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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."	A 145	observation, monitoring of vital signs and neurological status. • The Hospital's Medication Administration Policy has been revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration.	11/27/18
A 364	6. Review of the education records revealed the education began in March 2018, more than 2 months after the event. 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		• The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The Hospital determined that it has in	

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A 364	<p>Continued From page 38 (Patient #1) patient deaths reviewed.</p> <p>The findings included:</p> <p>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..."</p> <p>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,</p>	A 145	<p>place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no updates to the SOP for Moderate Sedation are required.</p> <ul style="list-style-type: none"> • <u>Training</u>: By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the Transport Policy, High Alert 	12/3/18

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A 364	<p>Continued From page 39</p> <p>apparently due to...regardless of the interval between event and time of death to the...Medical Examiner's Office..."</p> <p>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..."</p> <p>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</p>	A 145	<p>Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide regular updates to directors of these departments to ensure compliance.</p> <ul style="list-style-type: none"> • <u>Monitoring</u>: Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non-compliance, inconsistencies or 	12/3/18

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A 364	Continued From page 40 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	A 145	questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee. The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes: <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the override list, based on the work group's determination that the 	

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A 364	<p>Continued From page 41</p> <p>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..."</p> <p>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 than 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..."</p> <p>Review of the hospital's Occurrence Reporting:</p>	A 145	<p>clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the first two letters of "Paralyzing Agent" - which will then pull up the list of 	11/27/18

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A 364	<p>Continued From page 42</p> <p>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..."</p> <p>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)..."</p> <p>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</p>	A 145	<p>Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be effective in both eStar and AcuDose as of November 27, 2018. Effective on November 27, 2018, this updated procedure is documented by an amendment to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients, which are incorporated into the High Alert Medications Policy. These charts have been amended to list the four (4) specific Paralyzing Agents available at the Hospital, and to reflect the updated nomenclature of "Paralyzing Agent [medication name]".</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement warning in AcuDose and eStar, stating: "WARNING: PARALYZING AGENT - Causes Respiratory Arrest – Patient Must Be Ventilated." The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, effective on 	11/27/18

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A 364	<p>Continued From page 44</p> <p>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.</p> <p>Interview with (b)(6) 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..."</p> <p>(b)(6) was asked if he/she talked to the family and were they told about the medication error, and (b)(6) stated, "Just the husband, I don't remember if they asked any questions."</p> <p>Interview with (b)(6) 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. (b)(6) 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. (b)(6) stated that he/she could not remember. (b)(6) 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.</p>	A 145	<p>an Independent Double Check conducted by two licensed registered nurses prior to the administration of a Paralyzing Agent, where electronic clinical systems prompt dual sign off for bolus doses and upon the following for infusions:</p> <ul style="list-style-type: none"> o Initiation of infusion o Change of container o Handover <p>The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, which revisions are scheduled to be approved on November 27, 2018, to specify the Specific Safety Strategy that all Paralyzing Agents require such Independent Double Check.</p> <p><u>Training:</u> By November 26, 2018, every nurse and paramedic who work in an area of the Hospital where Paralyzing Agents are available in AcuDose dispensing cabinets, are required to complete an online training module outlining the process changes, Independent Double Check, vial packaging and naming convention changes. Any nurse or paramedic staff member required to complete such training, and who has not completed the computer-based training prior to November 27, 2018 for any reason,</p>	<p>11/27/18</p> <p>11/26/18</p>

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A 364	Continued From page 45 <p>(b)(6) was asked if he/she had any communication with the family regarding the event. (b)(6) stated that he/she talked to someone, distant relatives. He/She stated that he/she did not talk to the immediate family.</p> <p>Telephone interview with the (b)(6) (b)(6) in the Medical Examiners office on 11/5/18 at 10:01 AM, the (b)(6) was asked about (Named Patient #1) and what was reported to them regarding Patient #1's death, and the (b)(6) 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..."</p> <p>The (b)(6) was asked to describe the process when a physician reports a death, and the (b)(6) 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."</p> <p>The (b)(6) was given the information for Patient #1 and he/she looked up his/her case. The (b)(6) 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 (b)(6) 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..."</p> <p>The name of the drug was not disclosed to the ME.</p>	A 145	including being on vacation or not scheduled to work at the Hospital during the time period, will not be permitted to begin their next shift at the Hospital without first completing the required training. The Hospital is monitoring the completion of the required training programs, and as of November 21, 2018, 1,334 individuals, which is 53% percent of the Hospital's staff members required to receive the education, had completed the training requirement.	11/27/18
A 385	NURSING SERVICES CFR(s): 482.23		<ul style="list-style-type: none"> <u>Monitoring</u>: The Hospital will implement several measures to monitor compliance with the updated medication administration requirements. Beginning on November 27, 2018, the Hospital's Enterprise Medication Safety Officer, in collaboration with the Chief Nursing Officers, Executive Pharmacy Leadership, and Chief of Staff, will compile monthly reports of overrides from AcuDose cabinets for paralyzing agents, which will be reviewed at the medication safety committee, as well as on the unit level, and assessed for appropriateness. Such monthly reporting will be ongoing, and continue for three months following November 27, 2018. Thereafter, the 	

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A 385	<p>Continued From page 46</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The findings included:</p> <p>1. The hospital nursing services failed to ensure the correct medication was administered.</p> <p>Refer to A-0395</p> <p>2. The hospital nursing services failed to ensure medications were administered correctly per the physician's order and failed to ensure the nurse adhered to standards of practice and facility policies.</p> <p>Refer to A-0405</p>	A 145	<p>Enterprise Medication Safety Officer will continue to periodically review and provide override performance reports as part of ongoing medication safety committee work.</p> <p>In addition, beginning on November 27, 2018 and continuing on a monthly basis until 100% compliance is achieved, Hospital's Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p> <p>In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the preparation of drugs and safe medication practices. All nurse</p>	11/27/18

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A 385	Continued From page 47 3. The hospital failed to ensure nursing services correctly administered an IV drug and monitored for side effects after administration.	A 145	<p>residents, who are new graduate registered nurses hired with less than six months of nursing experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.</p> <ul style="list-style-type: none"> Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and based on the issues revealed in 	
A 395	<p>Refer to A-0409 RN SUPERVISION OF NURSING CARE CFR(s): 482.23(b)(3)</p> <p>A registered nurse must supervise and evaluate the nursing care for each patient.</p> <p>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 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.</p> <p>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.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 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, 			

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A 395	<p>Continued From page 48</p> <p>such as...respiratory distress...NURSING ALERT...The nurse is ultimately accountable for the drug administered..."</p> <p>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.</p> <p>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.</p> <p>The facility's "High Alert Medications Chart: Adult Patients Revised May 2018" did not list any moderate sedation agents such as Versed.</p>	A 145	<p>results of the audits described herein.</p> <p>The Hospital has reviewed its policies and procedures related the role of the "Help All Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of 	11/20/18

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A 395	<p>Continued From page 49</p> <p>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..."</p> <p>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.</p> <p>There was no documentation in Patient #1's medical record that Vecuronium or Versed was administered to her on 12/26/17.</p> <p>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..."</p> <p>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.</p>	A 145	<p>Care document on an annual basis to ensure duties of the position remain complete and accurate.</p> <p>The Hospital has reviewed its policies and procedures related to state reporting, and has made the following changes:</p> <ul style="list-style-type: none"> The Hospital reviewed its Occurrence Reporting: Patient and Visitor policy, which outlines requirements of every Hospital employee, attending physician and house staff member to report certain occurrences to the Hospital's Office of Risk and Insurance Management, either through the online occurrence reporting system or through a phone call to Risk Management. The Hospital has revised the Occurrence Reporting: Patient and Visitor policy to require Risk Management to report any a) incidents of abuse, neglect, or misappropriation reported to the Hospital department as complaints for certification processes; b) strike by staff; c) external disaster impacting a Hospital facility; d) disruption of any service vital to the continued safe operation of the Hospital facility, or to the health and safety of its patients and personnel; and e) fires at a Hospital facility that disrupt the provision of patient care services or 	11/27/18

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A 395	<p>Continued From page 50</p> <p>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..."</p> <p>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..."</p> <p>Review of the Automatic Dispensing Cabinet (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).</p> <p>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.</p> <p>Interview with the (b)(6) on 11/1/18 at 12:36 PM in conference room 167 the (b)(6) 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 (b)(6) (b)(6) stated, "No..."</p> <p>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</p>	A 145	<p>cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires. These policy revisions are scheduled to be approved by Executive Policy Committee of the Medical Center Medical Board effective November 27, 2018. The Occurrence Reporting: Patient and Visitor policy places the responsibility for reporting to the Tennessee Department of Health pursuant to the Health Data Reporting Act of 2002 with the Office of Risk and Insurance Management.</p> <p>Effective on November 27, 2018, the Hospital will implement a revised procedure during the established weekly meeting of the Event Review Committee to include regular evaluations of whether occurrences reported to the Office of Risk and Insurance Management require a report to the Tennessee Department of Health, pursuant to state law requirements. The Event Review Committee reviews patient events with harm or potential harm on a weekly basis, to identify those events which may require an Event Analysis pursuant to the Hospital policies, further investigation by Risk and Insurance Management,</p>	11/27/18

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A 395	<p>Continued From page 51</p> <p>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.</p> <p>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 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..."</p> <p>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</p>	A 145	<p>external reporting, or other potential safety or risk issues. The Event Review Committee is a Quality Improvement Committee (QIC) as defined pursuant to TCA §§ 63-1-150 and 68-11-272 and is comprised of representatives from Risk and Insurance Management; Quality, Safety, and Risk Prevention; and Patient Safety Officers. The Event Review Committee reports to the Self Insurance Trust, which reports to the Hospital Medical Center Medical Board. The participants of the Event Review Committee have been informed of the changes to the Occurrence Reporting policy and these additional procedures. The Senior Vice President of Quality, Safety and Risk Prevention and the Vice President of Risk and Insurance Management will continue participate in such weekly committee meetings and will monitor state reporting processes to ensure the Hospital reports as required by state and federal law. Further, the Hospital is currently communicating with the Tennessee Department of Health regarding additional guidance on reportable events under state law.</p> <ul style="list-style-type: none"> The Hospital has reviewed its policy outlining reporting requirements to 	11/27/18

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A 395	<p>Continued From page 52</p> <p>pulselessness on [his/her] arterial line..."</p> <p>Interview with the (b)(6) on 10/31/18 beginning at 3:15 PM, in conference room 167, the (b)(6) was asked about his/her role regarding [Named Patient #1]. The (b)(6) 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 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 (b)(6) 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..."</p> <p>Telephone interview with (b)(6) on 11/5/18 beginning at 4:41 PM, (b)(6) was asked to describe the circumstances leading up to Patient #1's death beginning on Tuesday 12/26/17 (b)(6) 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" (b)(6) 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</p>	A 145	<p>the Davidson County Medical Examiner, including its Deaths Requiring Reporting to the Medical Examiner policy (hereinafter, "Medical Examiner Policy"). The Hospital has amended the Medical Examiner Policy, which amendments are scheduled to be approved on November 27, 2018, to clarify that all details supporting a decision of: a) a suspicious, unusual or unnatural death, including unexplained surgical and anesthetic deaths, and b) death during or as a result of a diagnostic or therapeutic procedure, medication error, or adverse, allergic, or toxic reaction to a therapeutic agent, shall be reported to the Medical Examiner. The revised Medical Examiner Policy also requires all conversations with the Medical Examiner's Office to be documented in the patient's medical record, including the rationale for reporting pursuant to the criteria outlined in the Policy.</p> <ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring every Attending Physician and House Staff to complete education regarding the revised Medical Examiner Policy requirements, reporting requirements under state law, and documentation in the medical record 	12/3/18

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A 395	Continued From page 53 PET scan procedure or they would have to send him/her back and reschedule it. (b)(6) stated he/she searched for the Versed under Patient #1's profile in the ADC and (b)(6) couldn't find it. (b)(6) stated that he/she then chose the override setting on the ADC and searched for the Versed. (b)(6) 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. (b)(6) stated he/she took 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. (b)(6) verified he/she did not re-check the name on the vial. (b)(6) stated he/she grabbed a sticker from the patient's file, a handful of flushes, alcohol swabs, a blunt tip needle. (b)(6) 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. (b)(6) was asked how long it took him/her to get to the Radiology department PET scan, and (b)(6) (b)(6) stated, "5 minutes or less, it was my first time to go to PET scan, I had to ask for directions". (b)(6) 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". (b)(6) stated, "I reconstituted the medication and measured the amount I needed" The (b)(6) stated Radiology Technician #1 was there at the time he/she (b)(6) administered the medication IV to Patient #1. (b)(6) stated he/she left the Radiology PET scan area after he/she	A 145	under the Policy, as well as documenting communications and disclosure with family and/or patient representative. • <u>Monitoring</u> : The Chief of Staff, Office of Decedent Affairs and Quality, Safety and Risk Prevention will review Medical Examiner reporting to ensure the Hospital reports as required by state law. Additionally, this group will conduct audits of a designated number of patients who died under circumstances potentially reportable under the Medical Examiner Policy, randomly selected, in order to assess compliance with state reporting requirements. In the event such an audit reveals non-compliance, inconsistencies or questions, the Office of Decedent Affairs will elevate these issues to the VUMC Quality Steering Committee to determine whether additional steps are required for compliance, such as targeted education and/or training.	
		A 286	The Hospital has reviewed its policies and procedures related to its Quality Assurance and Performance Improvement (QAPI) process, and has committed to ensure comprehensive and robust investigation and implementation of safety measures:	

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A 395	Continued From page 54 had administered the medication to Patient #1. (b)(6) was asked how much medication did he/she administer to Patient #1, and the (b)(6) stated, "I can't remember, I am pretty sure I gave [him/her] 1 milliliter. (b)(6) was asked what was done with any left over medication, and the (b)(6) stated, "I put the left over in the baggie and gave it to [Named RN #2]..." (b)(6) was asked what he/she did after administering the medication to Patient #1, and the (b)(6) stated he/she left Patient #1 in Radiology. (b)(6) confirmed that he/she did not monitor Patient #1 after the medication was administered. (b)(6) was asked what happened next and the (b)(6) 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". (b)(6) 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 (b)(6) stated he/she, Physician #2, and the Charge Nurse moved Patient #1 back to the ICU. (b)(6) 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". (b)(6) stated RN #2 approached him/her and asked, "Is this the med you gave [him/her]?" and (b)(6) responded "yes". (b)(6) then stated RN #2 said, "This isn't Versed, It's Vecuronium."	A 286	<ul style="list-style-type: none"> The Hospital has reviewed its current procedures in place to ensure a thorough and prompt analysis of a critical adverse event, near misses and all the causes, and implementation of preventive actions that include implementing additional safety parameters as needed. The Hospital's existing QAPI program is typically initiated at the department or unit level, or through a report from staff through the online occurrence reporting system. Reported events are assessed by the Office of Risk and Insurance Management, Quality Safety and Risk Prevention, and operational leadership, and may be analyzed by the Event Review Committee. Each event report is reviewed locally by the designated manager and Clinical Risk Manager, before being referred to the applicable Hospital safety team in which the event occurred. The Safety Teams use standardized tools to assess each case for the potential of being a Serious Safety Event ("SSE"). A clinical review is performed to assess if there were potential deviations in generally accepted practices that resulted in patient harm. If it is deemed so, then the SSE Leadership team for the entity is called together. The applicable SSE Leadership team is 	

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A 395	<p>Continued From page 55</p> <p>(b)(6) 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.</p> <p>(b)(6) was asked if he/she documented he/she had administered the Vecuronium in Patient #1's medical record. (b)(6) 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."</p> <p>(b)(6) was asked if he/she could remember how much Vecuronium he/she administered to Patient #1, and (b)(6) stated, "I would have given her 1 milligram."</p> <p>(b)(6) 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."</p> <p>(b)(6) 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"</p> <p>Refer to A 144 and A145.</p>	A 286	<p>comprised of the Hospital's executive leaders (Chief Executive Officer, Chief Nursing Officer, Chief Operating Officer, Chief of Staff, Risk Management and other designees). The SSE Leadership team reviews the case and then votes on the SSE. This procedure creates situational awareness and accountability for organizational leaders. Once the SSE is confirmed, a Serious Safety Event Notification goes out to Hospital leadership across the health system. An SSE analysis is conducted and includes frontline clinicians, those directly involved with the case, unit leadership, support teams and other departments. Each case is unique and participants are invited relative to their role in the event. The analysis is facilitated by members of the Hospital Safety team, with Risk Management and physician leaders in Quality and Patient Safety roles who participate as well. An action plan is developed and distributed to the participants for implementation. Where the plan includes requirements for training of appropriate personnel, such training is initiated promptly. On a monthly basis, SSEs and the associated action plans are presented to the Hospital's executive team members</p>	

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		A 286	<p>in their respective Quality Committees and summary reports at the Hospital Quality Steering Committee. The SSE analysis process has also been reviewed in detail with the VUMC Board Quality and Safety Committee, which receives reports at each meeting regarding Hospital quality and safety initiatives and concerns from the Deputy CEO of VUMC. The Senior Vice President of Quality, Safety and Risk Prevention will monitor the QAPI program to ensure comprehensive and robust investigation and implementation of safety measures.</p> <p>The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond critically ill patients. As such, the newly amended policy is titled "Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, 	11/27/18

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		A 286	<p>supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the monitoring to be based on the patient's condition, type of medication, and route. Documentation will be in accordance with VUMC's Medication Administration Policy. The</p>	

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		A 286	<p>revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration.</p> <ul style="list-style-type: none"> The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The Hospital determined that its has in place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are 	

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		A 286	<p>continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no updates to the SOP for Moderate Sedation are required.</p> <ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the Transport Policy, High Alert Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, 	12/3/18	

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		A 286	<p>appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide regular updates to directors of these departments to ensure compliance.</p> <ul style="list-style-type: none"> <u>Monitoring</u>: Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non-compliance, inconsistencies or questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and 	12/3/18

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		A 286	<p>training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee.</p> <p>The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes:</p> <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the override list, based on the work group's determination that the clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's 	

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		A 286	<p>Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the first two letters of "Paralyzing Agent" - which will then pull up the list of Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are 	11/27/18

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		A 286	<p>attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be effective in both eStar and AcuDose as of November 27, 2018. Effective on November 27, 2018, this updated procedure is documented by an amendment to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients, which are incorporated into the High Alert Medications Policy. These charts have been amended to list the four (4) specific Paralyzing Agents available at the Hospital, and to reflect the updated nomenclature of "Paralyzing Agent [medication name]".</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement warning in AcuDose and eStar, stating: "WARNING: PARALYZING AGENT - Causes Respiratory Arrest – Patient Must Be Ventilated." The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, effective on November 27, 2018, to specify this pop-up warning as a Specific Safety Strategy for PARALYZING AGENTS. 	11/27/18	

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		A 286	<p>prompt dual sign off for bolus doses and upon the following for infusions:</p> <ul style="list-style-type: none"> o Initiation of infusion o Change of container o Handover <p>The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, which revisions are scheduled to be approved on November 27, 2018, to specify the Specific Safety Strategy that all Paralyzing Agents require such Independent Double Check.</p> <p><u>Training:</u> By November 26, 2018, every nurse and paramedic who work in an area of the Hospital where Paralyzing Agents are available in AcuDose dispensing cabinets, are required to complete an online training module outlining the process changes, Independent Double Check, vial packaging and naming convention changes. Any nurse or paramedic staff member required to complete such training, and who has not completed the computer-based training prior to November 27, 2018 for any reason, including being on vacation or not scheduled to work at the Hospital during the time period, will not be permitted to begin their next shift at the Hospital without first completing</p>	<p>11/27/18</p> <p>11/26/18</p>

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		A 286	<p>the required training. The Hospital is monitoring the completion of the required training programs, and as of November 21, 2018, 1,334 individuals, which is 53% percent of the Hospital's staff members required to receive the education, had completed the training requirement.</p> <ul style="list-style-type: none"> <u>Monitoring</u>: The Hospital will implement several measures to monitor compliance with the updated medication administration requirements. Beginning on November 27, 2018, the Hospital's Enterprise Medication Safety Officer, in collaboration with the Chief Nursing Officers, Executive Pharmacy Leadership, and Chief of Staff, will compile monthly reports of overrides from AcuDose cabinets for paralyzing agents, which will be reviewed at the medication safety committee, as well as on the unit level, and assessed for appropriateness. Such monthly reporting will be ongoing, and continue for three months following November 27, 2018. Thereafter, the Enterprise Medication Safety Officer will continue to periodically review and provide override performance 	11/27/18	

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		A 286	<p>reports as part of ongoing medication safety committee work.</p> <p>In addition, beginning on November 27, 2018 and continuing on a monthly basis until 100% compliance is achieved, Hospital's Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p> <p>In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the preparation of drugs and safe medication practices. All nurse residents, who are new graduate registered nurses hired with less than six months of nursing</p>	11/27/18

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		A 286	<p>experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.</p> <ul style="list-style-type: none"> Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and based on the issues revealed in results of the audits described herein. <p>The Hospital has reviewed its policies and procedures related the role of the "Help All</p>		

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		A 286	<p>Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of Care document on an annual basis to ensure duties of the position remain complete and accurate. 	11/20/18

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		A 364	<p>The Hospital has reviewed its policies and procedures related to state reporting, and has made the following changes:</p> <ul style="list-style-type: none"> The Hospital reviewed its Occurrence Reporting: Patient and Visitor policy, which outlines requirements of every Hospital employee, attending physician and house staff member to report certain occurrences to the Hospital's Office of Risk and Insurance Management, either through the online occurrence reporting system or through a phone call to Risk Management. The Hospital has revised the Occurrence Reporting: Patient and Visitor policy to require Risk Management to report any a) incidents of abuse, neglect, or misappropriation reported to the Hospital department as complaints for certification processes; b) strike by staff; c) external disaster impacting a Hospital facility; d) disruption of any service vital to the continued safe operation of the Hospital facility, or to the health and safety of its patients and personnel; and e) fires at a Hospital facility that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with 	11/27/18	

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		A 364	<p>preventing fires. These policy revisions are scheduled to be approved by Executive Policy Committee of the Medical Center Medical Board effective November 27, 2018. The Occurrence Reporting: Patient and Visitor policy places the responsibility for reporting to the Tennessee Department of Health pursuant to the Health Data Reporting Act of 2002 with the Office of Risk and Insurance Management.</p> <p>Effective on November 27, 2018, the Hospital will implement a revised procedure during the established weekly meeting of the Event Review Committee to include regular evaluations of whether occurrences reported to the Office of Risk and Insurance Management require a report to the Tennessee Department of Health, pursuant to state law requirements. The Event Review Committee reviews patient events with harm or potential harm on a weekly basis, to identify those events which may require an Event Analysis pursuant to the Hospital policies, further investigation by Risk and Insurance Management, external reporting, or other potential safety or risk issues. The Event Review Committee is a Quality Improvement Committee (QIC) as</p>	11/27/18	

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		A 364	<p>defined pursuant to TCA §§ 63-1-150 and 68-11-272 and is comprised of representatives from Risk and Insurance Management; Quality, Safety, and Risk Prevention; and Patient Safety Officers. The Event Review Committee reports to the Self Insurance Trust, which reports to the Hospital Medical Center Medical Board. The participants of the Event Review Committee have been informed of the changes to the Occurrence Reporting policy and these additional procedures. The Senior Vice President of Quality, Safety and Risk Prevention and the Vice President of Risk and Insurance Management will continue participate in such weekly committee meetings and will monitor state reporting processes to ensure the Hospital reports as required by state and federal law. Further, the Hospital is currently communicating with the Tennessee Department of Health regarding additional guidance on reportable events under state law.</p> <ul style="list-style-type: none"> The Hospital has reviewed its policy outlining reporting requirements to the Davidson County Medical Examiner, including its Deaths Requiring Reporting to the Medical Examiner policy (hereinafter, 	11/27/18

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		A 364	<p>"Medical Examiner Policy"). The Hospital has amended the Medical Examiner Policy, which amendments are scheduled to be approved on November 27, 2018, to clarify that all details supporting a decision of: a) a suspicious, unusual or unnatural death, including unexplained surgical and anesthetic deaths, and b) death during or as a result of a diagnostic or therapeutic procedure, medication error, or adverse, allergic, or toxic reaction to a therapeutic agent, shall be reported to the Medical Examiner. The revised Medical Examiner Policy also requires all conversations with the Medical Examiner's Office to be documented in the patient's medical record, including the rationale for reporting pursuant to the criteria outlined in the Policy.</p> <ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring every Attending Physician and House Staff to complete education regarding the revised Medical Examiner Policy requirements, reporting requirements under state law, and documentation in the medical record under the Policy, as well as documenting communications and disclosure with family and/or patient representative. 	12/3/18

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		A 364	<ul style="list-style-type: none"> Monitoring: The Chief of Staff, Office of Decedent Affairs and Quality, Safety and Risk Prevention will review Medical Examiner reporting to ensure the Hospital reports as required by state law. Additionally, this group will conduct audits of a designated number of patients who died under circumstances potentially reportable under the Medical Examiner Policy, randomly selected, in order to assess compliance with state reporting requirements. In the event such an audit reveals non-compliance, inconsistencies or questions, the Office of Decedent Affairs will elevate these issues to the VUMC Quality Steering Committee to determine whether additional steps are required for compliance, such as targeted education and/or training. 	
		A 385	<p>The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond 	11/27/18

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		A 385	critically ill patients. As such, the newly amended policy is titled "Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the		

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		A 385	<p>monitoring to be based on the patient's condition, type of medication, and route. Documentation will be in accordance with VUMC's Medication Administration Policy. The Transport Policy further states that such monitoring may include, but is not limited to, direct observation, vital signs, and neuro checks. The revised Transport Policy further requires appropriate documentation to be completed in the patient's medical record upon leaving and returning to the unit, including the times the patient leaves and returns to the unit.</p> <ul style="list-style-type: none"> The Hospital has revised its High Alert Medication Policy, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving administration of high alert medications. Specifically, the amended High Alert Medication Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may 	11/27/18	

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		A 385	<p>include, but is not limited to, direct observation, monitoring of vital signs and neurological status.</p> <ul style="list-style-type: none"> The Hospital's Medication Administration Policy has been revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration. The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The 	11/27/18	

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		A 385	<p>Hospital determined that it has in place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no updates to the SOP for Moderate Sedation are required.</p> <ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the 	12/3/18	

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		A 385	<p>Transport Policy, High Alert Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide regular updates to directors of these departments to ensure compliance.</p> <ul style="list-style-type: none"> <u>Monitoring</u>: Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non- 	12/3/18

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		A 385	<p>compliance, inconsistencies or questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee.</p> <p>The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes:</p> <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the 	

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		A 385	<p>override list, based on the work group's determination that the clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the 	11/27/18

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		A 385	<p>first two letters of "Paralyzing Agent" - which will then pull up the list of Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be effective in both eStar and AcuDose as of November 27, 2018. Effective on November 27, 2018, this updated procedure is documented by an amendment to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients, which are incorporated into the High Alert Medications Policy. These charts have been amended to list the four (4) specific Paralyzing Agents available at the Hospital, and to reflect the updated nomenclature of "Paralyzing Agent [medication name]".</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement warning in AcuDose and eStar, stating: "WARNING: PARALYZING AGENT - Causes Respiratory Arrest – Patient Must Be Ventilated." The Hospital has amended the High Alert Medications 	11/27/18	

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		A 385	<p>Charts for both Adult Patients and Pediatric Patients, effective on November 27, 2018, to specify this pop-up warning as a Specific Safety Strategy for PARALYZING AGENTS.</p> <ul style="list-style-type: none"> On November 27, 2018, the Hospital will implement new procedures for shrink wrap packaging to be added to all vials of Paralyzing Agents dispensed in AcuDose throughout the Hospital, and effective November 27, 2018 amendments to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients will be approved to specify a Specific Safety Strategy that all Paralyzing Agents dispensed in AcuDose cabinets throughout the Hospital will have shrink wrap packaging. The Hospital Executive Pharmacy Leadership will monitor compliance with the required shrink wrap packaging of Paralytic Agents by conducting random audits of all AcuDose cabinets throughout the hospital and validating packaging compliance for a minimum of three months of consecutive 100% compliance. As of November 27, 2018, the Hospital will finalize and implement new procedures to require the 	<p>11/27/18</p> <p>11/27/18</p>

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		A 385	<p>computer-based training prior to November 27, 2018 for any reason, including being on vacation or not scheduled to work at the Hospital during the time period, will not be permitted to begin their next shift at the Hospital without first completing the required training. The Hospital is monitoring the completion of the required training programs, and as of November 21, 2018, 1,334 individuals, which is 53% percent of the Hospital's staff members required to receive the education, had completed the training requirement.</p> <ul style="list-style-type: none"> <u>Monitoring</u>: The Hospital will implement several measures to monitor compliance with the updated medication administration requirements. Beginning on November 27, 2018, the Hospital's Enterprise Medication Safety Officer, in collaboration with the Chief Nursing Officers, Executive Pharmacy Leadership, and Chief of Staff, will compile monthly reports of overrides from AcuDose cabinets for paralyzing agents, which will be reviewed at the medication safety committee, as well as on the unit level, and assessed for appropriateness. Such monthly reporting will be ongoing, and 	11/27/18	

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		A 385	<p>continue for three months following November 27, 2018. Thereafter, the Enterprise Medication Safety Officer will continue to periodically review and provide override performance reports as part of ongoing medication safety committee work.</p> <p>In addition, beginning on November 27, 2018 and continuing on a monthly basis until 100% compliance is achieved, Hospital's Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p> <p>In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the</p>	11/27/18

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		A 385	<p>preparation of drugs and safe medication practices. All nurse residents, who are new graduate registered nurses hired with less than six months of nursing experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.</p> <ul style="list-style-type: none"> Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and 	

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		A 385	<p>based on the issues revealed in results of the audits described herein.</p> <p>The Hospital has reviewed its policies and procedures related the role of the "Help All Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of 	11/20/18	

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		A 385	each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of Care document on an annual basis to ensure duties of the position remain complete and accurate.		
		A 395	The Hospital has reviewed its policies and procedures related to monitoring of patients during and after medication administration and made the following changes: <ul style="list-style-type: none"> The Hospital has revised its policy previously titled Transport of the Critically Ill Patient, which revisions are scheduled to be approved on November 27, 2018, to broaden application of the policy beyond critically ill patients. As such, the newly amended policy is titled "Transport of Patients" (hereinafter, "Transport Policy"). This policy provides that every patient shall be transported with equipment, supplies, and staff appropriate to monitor and support the patient's physiological needs. The policy details that the level of care is maintained during transport and after arrival at the receiving department/unit, and describes specific monitoring and documentation requirements. The amended policy states that when a patient requires continuous 	11/27/18	

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		A 395	<p>monitoring, a clinical staff member is required to be available to receive handover of the patient pursuant to the Hospital's CL SOP - Clinical Handover Communication procedure. Any such handover will be documented in the medical record. In the event a clinical staff member is not available to receive the patient, the transporting clinical staff member must remain with the patient. Further, the Transport Policy states that patients receiving medications that could lead to respiratory depression and/or respiratory distress are monitored during and after transport, with the duration and frequency of the monitoring to be based on the patient's condition, type of medication, and route. Documentation will be in accordance with VUMC's Medication Administration Policy. The Transport Policy further states that such monitoring may include, but is not limited to, direct observation, vital signs, and neuro checks. The revised Transport Policy further requires appropriate documentation to be completed in the patient's medical record upon leaving and returning to the unit, including the</p>	

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		A 395	<p>times the patient leaves and returns to the unit.</p> <ul style="list-style-type: none"> The Hospital has revised its High Alert Medication Policy, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving administration of high alert medications. Specifically, the amended High Alert Medication Policy states that the patient's clinical status is monitored to evaluate patient response to medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neurological status. The Hospital's Medication Administration Policy has been revised, which revisions are scheduled to be approved on November 27, 2018, to detail required monitoring of patients receiving medications. Specifically, the amended Medication Administration Policy states that the patient's clinical status is monitored to evaluate patient response to 	11/27/18	
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		A 395	<p>medication and/or adverse reactions, and the duration and frequency of monitoring is based on the patient's condition, the type of medication, and route of administration. Such monitoring may include, but is not limited to, direct observation, monitoring of vital signs and neuro checks. The Medication Administration Policy has been further amended to require specific documentation in the medical record regarding medication administration.</p> <ul style="list-style-type: none"> The Hospital reviewed its policies and procedures related to moderate sedation, specifically the Standard Operating Procedure for Moderate Sedation, to ensure sufficient safeguards are in place. The Hospital determined that its has in place comprehensive guidance regarding the administration of moderate sedation, specifically including procedures for ensuring patients receiving sedation are continuously observed and physiologically monitored throughout the sedation period by a nurse, advanced practice nurse, physician, or other qualified and trained staff as approved by the Hospital's Sedation Committee. The SOP for Moderate Sedation details the post anesthesia recovery scoring system and score 		

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		A 395	<p>that is required to discontinue monitoring. The SOP for Moderate Sedation also includes conditions for transporting patients who have undergone moderate sedation, including required monitoring. The Hospital has determined that no updates to the SOP for Moderate Sedation are required.</p> <ul style="list-style-type: none"> <u>Training</u>: By December 3, 2018, the Hospital is requiring all managers, clinical staff leaders (CSLs), nurses, licensed practical nurses (LPNs), respiratory therapists and paramedics working in inpatient and procedural areas of the Hospital to complete education through its on-line education system, which addresses the updates to the Transport Policy, High Alert Medication Policy, and Medication Administration Policy including the requirements for monitoring patients during transport and during and after medication administration, appropriate handover, and related medical record documentation. No clinical staff member listed above will be able to begin shift after December 3rd without confirmation of training and subsequent competency testing. The Hospital's Chief Nursing Officers monitor this education requirement and provide 	12/3/18

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		A 395	<p>regular updates to directors of these departments to ensure compliance.</p> <ul style="list-style-type: none"> • <u>Monitoring</u>: Beginning on December 3, 2018 and continuing for the following three months, the Hospital's Chief Nursing Officers will oversee weekly chart reviews of 5 patients from each unit, randomly selected, to assess for compliance with improvement in medication safety, transport and monitoring of patients. Such patient records will be reviewed for documentation of the appropriate monitoring, handover communication, and documentation consistent with the Transport Policy, Medication Administration Policy and High Alert Medication Policy. In the event such an audit reveals non-compliance, inconsistencies or questions, the Chief Nursing Officers will follow-up with the unit level nurse managers for additional steps required to achieve compliance, such as targeted education and training. The Chief Nursing Officers will review monthly updates of such chart review audits to the VUMC Nursing Quality Committee. 	12/3/18

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		A 395	<p>The Hospital has reviewed its policies and procedures related to access and administration of Paralyzing Agents and made the following changes:</p> <ul style="list-style-type: none"> A multi-disciplinary work group comprised of Hospital leaders including Physicians, Pharmacy, Risk, Nursing, Quality, and Health Informatics was convened beginning on January 19, 2018 to assess Paralyzing Agents included on the override medication list. This workgroup determined to remove vecuronium from the AcuDose (Hospital's automated dispensing cabinet) override status list, which removal was approved by the VUMC Pharmacy, Therapeutics and Diagnostic Committee on February 23, 2018 and implemented on March 1, 2018. The work group determined that rocuronium would remain on the override list, based on the work group's determination that the clinical risks to patients of not having access to rocuronium outweighed the potential safety benefits from removing the Paralyzing Agent from override status. The Hospital's Medication Safety Officer in partnership with the VUMC Pharmacy, Therapeutics and Diagnostic Committee will reassess the Paralyzing Agents, including 		

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		A 395	<p>rocuronium, on the override list annually.</p> <ul style="list-style-type: none"> The Hospital has changed the naming convention from "Neuromuscular Blocking Agents", as referenced in certain policies, including the High Alert Medication Policy, to "Paralyzing Agents" for consistency throughout the Hospital. The Hospital has also standardized the nomenclature utilized for Paralyzing Agents across the Hospital in eStar (Hospital's electronic medical record) and AcuDose, such that both electronic systems present the name as "PARALYZING AGENT" followed by the medication name. Paralyzing Agents will no longer be able to be pulled up on the AcuDose override screen by typing in the drug name. Instead, "PARA" will be typed in - the first two letters of "Paralyzing Agent" - which will then pull up the list of Paralyzing Agents in the AcuDose cabinet. The four Paralyzing Agents are the <u>only</u> medications that result on both electronic systems in a search for "PARA". Signs are attached to the AcuDose cabinets indicating that "PARA" must be used to access Paralyzing Agents. The new nomenclature of "Paralyzing Agent: [medication name]" will be 	11/27/18	

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		A 395	<p>the Hospital, and effective November 27, 2018 amendments to the Hospital's High Alert Medications Charts for both Adult Patients and Pediatric Patients will be approved to specify a Specific Safety Strategy that all Paralyzing Agents dispensed in AcuDose cabinets throughout the Hospital will have shrink wrap packaging. The Hospital Executive Pharmacy Leadership will monitor compliance with the required shrink wrap packaging of Paralytic Agents by conducting random audits of all AcuDose cabinets throughout the hospital and validating packaging compliance for a minimum of three months of consecutive 100% compliance.</p> <ul style="list-style-type: none"> As of November 27, 2018, the Hospital will finalize and implement new procedures to require the additional Specific Safety Strategy for all Paralyzing Agents to include an Independent Double Check conducted by two licensed registered nurses prior to the administration of a Paralyzing Agent, where electronic clinical systems prompt dual sign off for bolus doses and upon the following for infusions: <ul style="list-style-type: none"> Initiation of infusion Change of container Handover 	11/27/18	

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		A 395	The Hospital has amended the High Alert Medications Charts for both Adult Patients and Pediatric Patients, which revisions are scheduled to be approved on November 27, 2018, to specify the Specific Safety Strategy that all Paralyzing Agents require such Independent Double Check.	11/27/18
			<p><u>Training:</u> By November 26, 2018, every nurse and paramedic who work in an area of the Hospital where Paralyzing Agents are available in AcuDose dispensing cabinets, are required to complete an online training module outlining the process changes, Independent Double Check, vial packaging and naming convention changes. Any nurse or paramedic staff member required to complete such training, and who has not completed the computer-based training prior to November 27, 2018 for any reason, including being on vacation or not scheduled to work at the Hospital during the time period, will not be permitted to begin their next shift at the Hospital without first completing the required training. The Hospital is monitoring the completion of the required training programs, and as of November 21, 2018, 1,334 individuals, which is 53% percent of</p>	11/26/18

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		A 395	<p>Chief Nursing Officers will review monthly reports of Independent Double Check, in order to verify compliance with the Independent Double Check procedure for Paralyzing Agents. Such monthly reporting will be provided to medication safety committees and the Hospital's Nursing Quality Committee.</p> <p>The Hospital also imposes the following general requirements for nurse training and education regarding its policies and procedures:</p> <p>In regard to nurse training on medication administration, medical record documentation, and monitoring of patients receiving medication, all newly hired nurses are required to complete computer-based training related to the preparation of drugs and safe medication practices. All nurse residents, who are new graduate registered nurses hired with less than six months of nursing experience, are required to complete such education regarding safe medication practices, as well as attend a workshop on medication safety. These trainings have been updated to include education as to the revisions to the Medication</p>	

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		A 395	<p>Policy, the new nomenclature for Paralyzing Agents, the updated requirements for monitoring patients receiving High Alert Medications.</p> <ul style="list-style-type: none"> Further, all nurses and nurse residents receive ongoing education on an annual basis regarding a variety of topics determined by Hospital nurse leaders, educators and staff. Nursing staff must validate competency in the identified topics between January and June of each calendar year through a variety of methods, including an online learning module, skill validation on a mannequin, observation of daily practice, etc. The Hospital will include medication administration, patient monitoring, documentation and other issues discussed in this Plan of Correction in such annual competencies, as appropriate and based on the issues revealed in results of the audits described herein. <p>The Hospital has reviewed its policies and procedures related the role of the "Help All Nurse", which is a type of resource nurse, and made the following changes:</p> <ul style="list-style-type: none"> The Hospital has updated Scope of Care documents in each department 	11/20/18	

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		A 395	that relies on a "Help All Nurse" (or similar position), in order to define the applicable role and duties. At the Hospital, "Resource Nurse" is generally used to describe a nursing role that usually does not take patient assignment during the shift but takes direction from the Clinical Staff Leader or Resource Staff Leader to assist other nurses as workloads demand, including rapid response teams, STAT calls, and transports. Resource Nurse roles in various departments include Float Nurse; Procedural Nurse; Admit Discharge, Transfer Nurse; and Patient Flow Nurse. The Scopes of Care were revised in intensive care units and non-intensive care units to define the applicable Resource Nurse role (including the "Help All Nurse" as applicable) by November 20, 2018. Nursing leadership of each Hospital department that utilizes such a Resource Nurse role will review the departments Scope of Care document on an annual basis to ensure duties of the position remain complete and accurate.		