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| A 000 | INITIAL COMMENTS<br><br>The following reflects the findings of the California Department of Public Health during the Complaint Validation Survey conducted on 3/22/21 to 3/26/21, and 3/29/21 to 4/1/21.<br><br>Complaint Number: 727021<br><br>Representing the Department:<br><br>35649, Health Facilities Evaluator Nurse (HFEN)<br>42344, Health Facilities Evaluator Nurse (HFEN)<br>42125, Medical Consultant<br>13095, Pharmaceutical Consultant II Specialist<br>41166, Pharmaceutical Consultant II Specialist<br>40903, Pharmaceutical Consultant II Specialist<br><br>Census: 311<br>Sampled Patient: 73<br><br>During this Complaint Validation Survey, the Hospital was not in compliance with four Conditions of Participation (CoP- Federal requirements health care organizations must meet in order to receive Medicare/Medicaid payment) set forth at 42 CFR Part 482.<br><br>The four Conditions of Participation not met are:<br>Compliance with Federal, State, and Local Laws<br>Governing Body<br>Medical Staff<br>Pharmaceutical Services | A 000 | | |
| A 020 | COMPLIANCE WITH LAWS<br>CFR(s): 482.11<br><br>Compliance with Federal, State and Local Laws<br><br>This CONDITION is not met as evidenced by: | A 020 | | |

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

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| A 020 | Continued From page 1<br>Based on interview and record review, the hospital failed to follow Federal and State laws that govern Health and Safety of Patients, Controlled Substances, and Determining the Death of a Patient as evidenced by:<br><br>1. The Governing Body failed to provide a process to prevent and intervene when the use of drug paraphernalia (any device or item used to inject or smoke a controlled substance/drug, i.e, syringes, needles, alcohol swabs) and illegal substances were used by staff on hospital premises. This failure place staff, visitors, and the public at risk for injury.<br>(Refer A0021).<br><br>2. The Governing Body failed to enforce controlled substance and dangerous drug policy and procedures for three of three Anesthesia Residents (physicians in training) [Resident 5, Resident 6, and Resident 7] who were required to give-up their responsibility and accountability in the administration and control of controlled substances and were directed to hand the controlled substances to their attending or supervising physician (doctor who supervises physicians in training) without regard for the controlled substance chain of custody (tracks controlled substances from the moment they are acquired to the moment they are administered and wasted). This failure resulted in these three Anesthesia Residents acting as potential proxies for the attending physician (MD 1) to obtain controlled substances, in which five of 73 sampled patients (Patient 4, 73, 69, 65, and 56) had documented larger doses of medications given for short procedures (4-7 minutes).<br>(Refer to A0021). | A 020 | | |

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| A 020 | Continued From page 2 | A 020 | | |

3. The hospital failed to ensure it has a process and safety measures that prevented the diversion and abuse of Propofol (Diprivan- a strong medication given into a vein and used to cause unconsciousness and if the dose is too high, it can make one stop breathing, and die) for one of one contracted staff (Scribe - SC 1) in the Emergency Department. This failure apparently resulted in the death of the Scribe. (Refer to A0021).

4. The Governing Body failed to ensure the hospital policy and procedures were developed for all hospital Providers and staff to account for the distribution, access, and waste of the divertible substance, Propofol to prevent diversion. This failure allowed easy access to a dangerous divertible medication, Propofol. (Refer to A0021).

5. The hospital failed to ensure medication reconciliation and diversion policy and procedures, and medical staff bylaws were followed for four of four Providers (MD 1, CRNA 4, CRNA 7, and Resident 14). This failure allowed drug theft, loss and/or diversion to go unchecked and escape detection. (Refer to A0021).

6. The hospital failed to abide by a competent patient's full code resuscitation directive (all necessary medical interventions to sustain life and intervene with life sustaining medical support) for one one sampled patient (Patient 1). This failure to follow Patient 1's life directions resulted in the withholding of the medical care and measures to preserve Patient 1's life and pronouncement of death of Patient 1 after injection of fentanyl (a narcotic pain medication) and removal of breathing tube.

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| A 020 | Continued From page 3<br>(Refer to A0021).<br><br>The cumulative effects of these systemic failures had the potential to negatively impact the safety and quality of care, treatment, and services of the patients, staff, and the public. | A 020 | | |
| A 021 | COMPLIANCE WITH LAWS<br>CFR(s): 482.11(a)<br><br>The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Hospital failed to:<br><br>1. Provide a process to prevent and intervene when the use of drug paraphernalia (any device or item used to inject or smoke a controlled substance/drug, i.e, syringes, needles, alcohol swabs) and illegal substances were used by staff on hospital premises. This failure place staff, visitors, and the public at risk for injury.<br><br>2. Enforce controlled substance and dangerous drug policy and procedures for three of three Anesthesia Residents (physicians who finished medical school and in training) [Resident 5, Resident 6, and Resident 7] who were required to give-up their responsibility and accountability in the administration and control of controlled substances and were directed to hand the controlled substances to their attending or supervising physician (doctor who supervises physicians in training) without regard for the controlled substance chain of custody (tracks controlled substances from the moment they are | A 021 | | |

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| A 021 | Continued From page 4 | A 021 | | |

acquired to the moment they are administered and wasted). This failure resulted in these three Anesthesia Residents acting as potential proxies for the attending physician (MD 1) to obtain controlled substances, in which five of 73 sampled patients (Patient 4, 73, 69, 65, and 56) had documented larger doses of medications given for short procedures (4-7 minutes).

3. Ensure it has a process and safety measures that prevented the diversion and abuse of Propofol (a strong medication given into a vein and used to cause unconsciousness and if the dose is too high, it can make one stop breathing, and die) for one of one contracted staff (Scribe - SC 1) in the Emergency Department. This failure apparently resulted in the death of the Scribe.

4. Ensure policy and procedures were developed for all hospital Providers to account for the distribution, access, and waste of the divertible substance, Propofol to prevent diversion. This failure allowed easy access to a dangerous divertible medication, Propofol.

5. Ensure medication reconciliation and diversion policy and procedures, and medical staff bylaws were followed for four of four Providers (MD 1, CRNA 4, CRNA 7, and Resident 14). This failure allowed drug theft, loss and/or diversion to go unchecked and escape detection.

6. Abide by a competent patient's full code resuscitation directive (all necessary medical interventions to sustain life and intervene with life sustaining medical support) for one one sampled patient (Patient 1). This failure to follow Patient 1's life directions resulted in the withholding of the medical care and measures to preserve Patient

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1's life and pronouncement of death of Patient 1 after injection of fentanyl and removal of breathing tube.

Findings:

1. During an interview on 3/23/21, at 6:15 PM, with Registered Nurse (RN 2), RN 2 stated, in addition to SC 1, he was aware of episodes of used syringes and needles, with evidence of a "white milky substance, Propofol".

During an interview on 3/23/21, at 8:30 PM, with Registered Nurse (RN 3), RN 3 stated, in addition to SC 1, on three separate occasions, she found contaminated syringes and needles, alcohol swabs, and sometimes blood in the ED (Emergency Department) bathrooms. She stated the syringes had "white substance. . .looked like Propofol" in them. RN 3 stated, she reported the episodes to RN 16. RN 3 stated, RN 16 notified the House Supervisor (HS) of the findings.

During an interview on 3/25/21, at 8:50 PM, with Registered Nurse (RN 1), RN 1 stated, "Syringes were found in a bathroom with white substance in them, not the bathroom SC 1 was found in. . .and during the code [resuscitation] we found more syringes". RN 1 stated, she "noticed Propofol was missing" from Patient 1. RN 1 stated this triggered, her, RN 2, RN 3, and RN 14, all to look for SC 1. RN 1 stated RN 3 said "we need to find him [SC 1], before he is dead."

During an interview on 3/26/21, at 10:18 AM, with Security officer (SO 1), SO 1 stated he wrote a report regarding the 12/22/2020 events of SC 1, and was given new information regarding syringes and needles found in ED bathrooms

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over the prior days. The report indicated "during the investigation staff members found syringes with a milky white substance, alcohol wipes, and blood in the staff restroom outside of Zone 3 that night and the night prior. The nursing staff were concerned a staff member was potentially using drugs in this location." SO 1 stated these incidents were not reported to security department. SO 1 stated, there are "no policies" if syringes are found on (Facility) grounds. . .bathrooms, parking lot, sidewalk . . .if syringes are found. . .glove-up, pick it up and throw it in the sharp container. . .no logs of syndromes [are kept]".

During an interview on 3/26/21 at 6:00 PM, with Security Officer Supervisor (SOS 1), SOS 1 stated he did not take the (Facility) security report on 12/22/20 regarding SC 1, but there was a "similar episode" the night before, on 12/20/20. It occurred in "Zone 3" where there are no cameras, "needles and syringes were found in the bathrooms". SOS 1 stated security "should be notified of all events regarding illegal substance and suspicious substances" on hospital grounds. SOS 1 stated he did not have a report for the event.

During an interview on 3/29/21, at 7:05 PM, with Emergency Department Physician (MD 7), MD 7 stated "housekeeping found syringes" in a staff ED bathroom, and clarified "not the bathroom SC 1 was found in." MD 7 stated the events were reported to the charge nurse, RN 3. MD 7 stated, staff was "concerned SC 1 was involved". MD 7 stated on 12/22/20, SC 1 was found in the ED public bathroom. MD 7 stated "needles" and "big syringes, 60 ml [milliliter]" of Propofol were found".

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| A 021 | Continued From page 7<br><br>During an interview on 3/31/21, at 3:40 PM, with House Supervisor (HS), HS stated Environmental Services (EVS) staff notified him of blood and used needles and syringes in a "secure area staff [ED] bathroom" HS stated EVS reported the episodes to security, ED team lead, ED nurses who in turn notified him. HS stated "it must be staff". HS stated he could not recall the day of the events and did not complete an occurrence report.<br><br>During a review of the electronic mail, titled "Urgent Message Drug Diversion Prevention," dated 2/8/21 at 2:25 PM, from the Director of Risk Management (DRM), provided by Risk Management, the email included a picture from EVSM report and ways to prevent and report "suspicious findings or signs of drug diversion" "for the safety and well-being of everybody. . .You can save a life". The email was sent to "District", but unclear who the email was sent to.<br><br>During an interview on 3/21/21, at 2:50 PM, with the Director of Environmental Service/ Laundry and Environmental Service Manager (DEVS) and Environmental Service Manager (EVSM), DEVS stated we received reports from EVS (environmental service) staff that syringes with a white liquid/blood, dirty used syringes, needles and/or paper were found in the ED staff bathroom. DEVS stated he recalls one email regarding these episodes, and forwarded them to Risk. EVMS stated the process for any item of concern or illegal drug use at (Facility), EVS staff is to call security and communicate with management. DEVS and EVSM stated MIDAS (incident reporting system) reports were not completed for any of the events. | A 021 | | |

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During a review of the electronic mail (email), dated 12/22/20, at 8:04 AM, the email with attached photo included email communication between DRM, DEVS, Chief of Human Resources (CHRO) and Emergency Department Nurse Manager (EDNM). The photo content of the email had used syringes, wrappers and blood in an ED bathroom found by EVS staff. The email indicated EVS staff identified used syringes, wrappers, and blood, "found yesterday morning", and "it was also said seen again this morning." The email indicated, CHRO wrote "another employee overdosed in a bathroom last night, but thinking it would have been another location." DEVS wrote, "Will follow-up with another staff member who also saw a syringe (not sure if it was the same location as yesterday morning)". DEVS could not determine how many syringes and needles were found and on what days. No occurrence reports were written and there were no other email exchanges.

During the Governing Body meeting on 4/1/21, at 12:20 PM, the CEO stated he was not aware of the episodes of used syringes and needles in the ED bathrooms.

During the Governing Board Meeting on 4/1/21, at 12:20 PM, the Chief Nursing Officer (CNO) stated, she was "aware" of episodes of the syringes and needles in the ED bathrooms in December 2020. CNO stated "took a rapid approach. . .interventional approach" for the needles and syringes and there is an "investigation".

During a review of the email, dated 2/8/21, at 2:25 PM, from DRM, the email indicated, "To:

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[Facility] Urgent, Subject: Drug Diversion Prevention. Drug diversion is a term used when an individual removes, takes, or find medications) that are prescribed for someone else and used them for him/herself. Examples: A patient is prescribed two pills - the person gives one pill to the patient and keeps one pill for themselves. . .person uses an empty syringe to remove medicine from an IV tubing to inject into themselves. . .A person finds medication and takes it home. . .What are suspicious findings or signs of drug diversion? Syringes or empty medication containers found in trash, bathroom, on counters, or other non-patient care areas. Blood and blood products in the trash in patient care setting not infusing. . .Syringes, needles, or medications being kept in unsecure locations. . .Count discrepancies. . .uncontrolled patient pain. . .Reporting findings is for the safety and well-being of everybody. Reporting suspicious findings can potentially save a life and prevent harm. For information see Policy HR 200". One of the pictures used in the email, appear to be similar to the MIDAS report.

2. During an interview on 3/26/21, at 4:05 PM, with Certified Registered Nurse Anesthetist (CRNA 1), CRNA 1 stated, MD 1 had a "cocktail-standard 5 mg [milligram, a unit of measure] of versed [medication that helps patients feel relaxed or sleepy before surgery or medical procedure] and 250 mcg [microgram, a unit of measure] of fentanyl [a narcotic pain medication], no matter how long the case was." CRNA 1 stated [Facility] "knew of it," MD 1 "diverting versed and fentanyl for years". CRNA 1 relayed her and other CRNA's concerns of MD 1's behavior, over use of controlled substances and diversion (unlawful channeling of regulated

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medication from legal sources to the illicit marketplace) in the summer of 2020 and again on January 2021 to Chief of Staff (MD 2) and/or Graduate Medical Education Program Director, Anesthesia (MD 4). CRNA 1 stated after the complaints in the summer of 2020, MD 1 continued to work, but mainly with residents (physicians in training) and rarely with CRNAs. CRNA 1 stated the provider who removes the controlled substance from the Pyxis (an automated drug dispenser) is responsible for it. CRNA 1 stated, "can't transfer controlled substances. . .they are given to a patient or wasted [discard unused portion]", and waste must be accounted for.

During an interview on 3/24/21, at 5:25 PM, with Chief, Department of Anesthesia (MD 3) MD 3 stated relationship with residents is akin to a "child-parent relationship" and residents have "inherent trust" of their attending physicians. "Residents have to trust their attendings." MD 3 described the process for residents managing control substance that he/she checked out from the Pyxis. MD 3 stated, during the first three year of residency training, the "residents are pulling [removing controlled substance from the Pyxis machine] medications for the attending/supervising MD and will prepare the medications for the surgical case. The resident will give the medications to the attending physician. The attending is "in charge of the meds . . .meds pushed", and "deciding what needs to be given" to the patient.

During a concurrent interview and record review, on 3/24/21, at 5:45 PM, with MD 3, five anesthesia patient records (Patients 73, 69, 65, 56 and 4) that involved residents and the

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attending physician (MD 1) were reviewed. The procedures were 4 to 7 minutes and large quantities of medications were given and the patients were discharged home shortly after. MD 3 stated the quantities of medications were much larger than one would be expected for short procedures. The following cases were reviewed:

Patient 73. For a four minute case on a young healthy female without medical issues and uneventful procedure, Patient 73 received fentanyl 150 mcg (typical dose 25 to 50 mcg) versed 4 mg (typical dose zero to 1 mg), Propofol 575 mg (typical dose 20 to 50 mg). Patient 73 went home shortly after.

Patient 69. For a seven minute case on a young healthy female without medical issues and uneventful procedure, Patient 69 received fentanyl 350 mcg (typical dose 25 to 50 mcg), versed 5 mg (typical dose zero to 1 mg), Propofol 512 mg (typical dose 20 to 100 mg). Patient 69 went home shortly after.

Patient 65. For a three-minute case on a young healthy female without medical issues and uneventful procedure, Patient 65 received fentanyl 250 mcg (typical dose 25 to 50 mcg) versed 5 mg (typical dose zero to 1 mg), Propofol 250 mg (typical dose 20 to 50 mg). Patient 65 went home shortly after.

Patient 56. Seventeen minute case on a young healthy male without medical issues and uneventful procedure, Patient 56 received fentanyl 700 mcg (typical dose 50 to 100 mcg), versed 7 mg (typical dose zero to 2 mg), Propofol 520 mg (typical dose 50 to 100 mg) and anesthetic gas (an inhaled gas used to cause

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unconsciousness and pain control, and non to minimal other meds needed except during induction [putting patients asleep for surgery]), Patient 56 went home shortly after.

Patient 4. For a five minute case on a young healthy female without medical issues and uneventful procedure, Patient 4 received fentanyl 250 mcg (typical dose 25 to 50 mcg) versed 2 mg (typical dose zero to 1 mg), Propofol 145 mg (typical dose 30 to 50 mg). Patient 4 went home shortly after.

During a concurrent interview and record review, on 3/29/21, at 4:05 PM, with MD 4, Patients' 73, 69, 65, and 56 anesthesia records that involved anesthesia residents and MD 1 were reviewed. All four patient anesthesia records indicated, "The procedures were 4 to 7 minutes and large quantities of medications were given and the patients were discharged home shortly after." MD 4 stated, the quantities of medications were larger than one would expect to give for short procedures, but he "wasn't there." In addition, MD 4 stated, residents have "inherent trust" that the attending will give the medications the patient what he/she told was given is true, and "in a subordinate position". MD 4 described the process for residents managing control substance that he/she checked out from the Pyxis. MD 4 stated attending physicians "chooses" the medications for the case. The resident will "obtain them from the Pyxis, draw them up into a syringe, label them, and give them to the attending physician. The attending will administer the intravenous medications.

During a concurrent interview and record review, on 3/29/21, at 5 PM, with MD 4, the hospital's

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policy and procedures titled, "Pyxis Anesthesia System (PAS) (RX 7.50.0), Medication Administration (PC 19), Dangerous Drugs: Theft/Loss (KDEP 11), Medication: Narcotics (PC 67), Occurrence Reporting Process (AP 100, Drugs and Alcohol (HR 200), Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse (AP 110) were reviewed. MD 4 stated, residents are employees of the hospital and must abide by all hospital policies and procedures. MD 4 stated, there are "short change artists" when reconciliation and diversion are concerned.

During an interview on 3/25/21, at 2:08 PM, with Anesthesia Resident PGY 3 (Resident 5), Resident 5 stated, she "never pushed [give intravenous, in a vein] meds [medications] on induction [putting patients asleep for surgery]. . .pushing meds is by supervising MD [physician]. . .Resident records the meds given". The supervising physician will direct her what to write.

During an interview on 3/26/21, at 11:51 AM, with Anesthesia Resident PGY 4 (Resident 7), Resident 7 stated, for every year in the anesthesia residency program, intravenous medications are given by the attending physician. Residents check them out from the Pyxis, "draw [put medication in a syringe] them up, label, dilute, date and give them to [physician]". Resident 7 stated, there are "typical requests from each attending, and depending on the attending. Resident 7 stated the attending will ask for the medication, including controlled substances to be handed over "in a kidney basin, plastic bags, on top of Pyxis, on the table- work station of the anesthesia machine. . .induction at the beginning of the case, [putting the patient to

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sleep] usually all meds [medications] are given" by the attending, the remaining medications are "given to a colleague/peer, attending". No reconciliation is completed. The resident will record what the attending directs.

During a concurrent interview and record review on 3/26/21, at 12:15 PM, Patient 65 and Patient 56 anesthesia records, two cases Resident 7 was involved in with MD 1 as the attending, were discussed and reviewed. Resident 7 could not recall why the quantity of medications were needed or why the patients were ready to go home so soon after the amounts of medications received. Resident 7 stated, the pharmacy will email the resident or provider if there are any controlled substance "discrepancies". "I [Resident 7] get an email, I correct the error, but I'm not necessarily the one who made the mistake. . .the attending [supervising physician of residents] pushed meds [medications given via a vein] during care. . . I didn't make mistake". "No matter who pulled [removed medications from Pyxis], the standard for CA 1-3 [anesthesia resident training years] attendings pushes meds" and resident records what the attending tells the resident to chart.

During a concurrent interview and record review on 3/25/21, 6:58 PM, with Anesthesia Resident PGY 4 (Resident 6), Patient 73 and Patient 4's anesthesia records, two cases Resident 6 was involved in with MD 1 as the attending, were discussed and reviewed, Resident 6 could not recall why the quantity of medications were needed or why the patients were ready to go home so soon after the amounts of medications received. Resident 6 stated, residents "trust" and there is "no suspicion" if the content of syringes

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are "false" or "incorrect". Resident 6 also stated medications, including controlled substances are left in the operating room unattended. Resident 6 stated, the attending will give the medications that the resident checked out from the Pyxis machine. She did state "whoever checked out [medications] from the Pyxis is responsible". Resident 6 stated she has not had education regarding medication reconciliation of chain of custody of controlled substance."

3. During an interview on 3/23/21, at 6 PM, with Registered Nurse (RN 2), RN 2 stated on the evening of 12/21/20, Scribe (SC 1- a person who performs patient documentation and clerical tasks on behalf of a physician) reported to work in the Emergency Department. His shift to work started 6 PM, on 12/21/20, in the ED and he was last seen in the ED after 12:36 AM, on 12/22/20. SC 1 was found unresponsive, pulseless, and not breathing in the bathroom on 12/22/20 at 2:12 AM, with two 20-30 syringes. RN 2 stated, two syringes were found on SC 1, "one 20-30 ml syringe that had enough remain in the syringe to know what it was. . .a white milky substance. . .looked like Propofol with a needle attached and the other filled with Propofol". The ED performed life-saving measures, but resuscitation was unsuccessful. RN 2 stated, there was a debriefing (a meeting held to discuss an event designed to provide support and gather feedback) and were asking where the Propofol came from-rooms 19, 20 and 25 were rooms that had Propofol infusing for patients.

During an interview on 3/23/21, at 8:15 PM, with Registered Nurse (RN 3), RN 3 stated she gathered RN 1, RN 2, and the Clinical Pharmacist ED (RPHED) to "check and look in every

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restroom, because she knew someone was dead."

During an interview on 3/24/21, at 2:35 PM, with Emergency Department Physician (MD 6), MD 6 stated SC 1 was working as MD 6's scribe. MD 6 stated SC 1 did not answer his calls or overhead pages for several hours. MD 6 stated he was the primary ED physician for [SC 1 /Patient 2]. MD 6 stated, he recognized Patient 2 as the Scribe when SC 1 was rushed to room 21 being resuscitated.

During an interview on 3/25/21, at 8:50 PM, with Registered Nurse (RN 1) RN 1 stated SC 1 did not answer calls or pages for several hours. RN 1 stated at around 2:00 AM, she "noticed Propofol was missing", about 3/4, from Patient 1's bottle. When she reported the episode to RN 3 and RPHED, other recurring events of syringes and needles in ED bathrooms came to mind. Something "clicked" about not being able to find SC 1 for several hours over the past few shifts, and "syringes were found in a bathroom with white substance in them." RN 1 stated RN 3 said "we need to find him [SC 1], before he is dead." RN 1 stated this triggered RN 1, RN 2, RN 3, RN 14, and RPHED to look for SC 1. RN 1 stated SC 1 was found with "white substances in the syringes and blood in the bathroom, and during the code we found more syringes with white substances. RN 1 stated MD 6 "questioned the RNs of the events" surrounding SC 1. RN 1 stated MD 6 knew about SC 1, how he was found and the "white substances in the syringes and blood in the bathroom. . .and during the code we found more syringes" with Propofol.

During an interview on 3/26/21, at 10:20 AM, with

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Security Officer (SO 1), SO 1 stated, "I received a call to go to the public bathroom between Zone 1 and Zone 2 in the ED. When I opened the door, the [Scribe 1] was on the floor, unresponsive, pale, looked like blood near his head. I opened the door fully and the ED staff recognized it as a Code (medical emergency) situation. The staff called for help and called a code in the bathroom. [SC 1] was taken to Room 21, being resuscitated." SO 1 stated "local police arrived at the facility and I assisted the police interview the ED staff." SO 1 stated he wrote a report which indicated, "during the investigation staff members found syringes with a milky white substance, alcohol wipes, and blood in the staff restroom outside of Zone 2 this night and the night prior. They had concerns a staff member was potentially using drugs in this location." SO 1 stated these incidents were not reported to security department. During the debriefing RN 3 also informed security she believed [SC 1] gained access to the drug by filling two syringes with Propofol container that was meant to be given to a patient in room 19 of the ED and went inside Zone 1 restroom where he ultimately injected himself with the drug.

During concurrent interview and review of the video footage, on 3/30/21, at 10:18 AM, with Security Services Manager (SSM), and Security Officer (SO 1), SSM stated, per the video footage, [SC 1] entered Patient 1's room, Room 19, in the ED Zone 2, on 12/21/20, at 12:34 AM. Near the door, [SC I] was opening a drawer containing syringes and drawer above it containing needles, and small wrapper was discarded in the trash. There is also an RN in the room. At the room entry, the Emergency Department Technician (EDT) and Environmental

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Services Staff (EVS) are tending to the trash. SSM stated, per the video footage, [SC 1] was seen leaving Patient 1's room on 12/21/20 at 12:36 AM, and entered an ED public bathroom. The video footage did not show SC 1 exiting the bathroom. SSM stated per the video footage, Security Officer (SO 1) responded to the request to open a locked bathroom. At 2:12:57 AM, SO 1 opens the door and a "swarm of staff" rush to the alcove entrance of the ED public bathroom. SO 1 identified RN 1, RN 2, RN 3 and RN 14, as entering the bathroom when the door opened. At 2:14:00 AM, SC 1 was on a gurney being wheeled to Room 21 in the ED Zone 2. There were many ED staff entering the room, and SO 1 identified MD 6, RN 1, RN 2, RN 3, RN 14, and EDT.

During a review of SC 1's Emergency Documentation, dated 12/22/20, the ED Physician Notes indicated, "Final Diagnosis: Cardiac arrest, cause, unspecified,"

During a review of SC 1's Cardiopulmonary Resuscitation Report (Code sheet), dated 12/22/20, the code sheet indicated, "MD 6 pronounced SC 1 dead at 2:33 AM."

During an interview on 3/29/21, at 7:05 PM, with Emergency Department Physician (MD 7), MD 7 stated [SC 1] was found in the ED public bathroom and was moved to room 21 for resuscitation. MD 7 stated "needles" and "big syringes, 60 ml" of Propofol was found.

During an interview on 3/30/21 at 7:50 PM, with RN 3, RN 3 stated, the "code was over," and another 20 ml syringe with Propofol was found in room 21 on the ground. RN 3 stated MD 7 and

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MD 6 were present when she reported it to the police, security, and EDNM. RN 3 stated, the police instructed her to "throw it away".

During an interview on 3/31/21, at 6:50 PM, with Emergency Department Technician (EDT), EDT stated he witnessed, after SC 1 resuscitation in room 21, "someone from room 21 [can't recall who] bringing a 60 ml syringe with a needle filled with what looked like Propofol. EDT stated the "whole room-RN 1, RN 3, RN 2, RN 14, MD 6, RT 1, residents knew about the Propofol".

During a concurrent interview and record review, on 3/26/21, at 2:45 PM, with Detective, Tulare County (DET), DET stated on 12/22/20, at 4:05 AM, he arrived at [Facility]. DET documentation indicated "two syringes were found next to him [SC 1]. One of the syringes was full with Propofol and the other was empty. ER staff additionally found several syringe needles in his pants pocket. . .soon after [SC 1] was found a nurse [RN 1] reported a Propofol bottle, which had been used on a previous patient, had medication missing from it. . .soon after SC 1's death. . .it is reasonable to conclude that SC 1 died due to accidental overdose". DET stated he did not receive the Propofol syringes to pass to the coroner for testing because the ED staff had discarded them.

4. During a concurrent interview and review of the drug manufacturer's insert on Propofol (sedation medication, on 3/29/21, at 4:05 PM, with Graduate Medical Education (GME Program Director, Anesthesia (MD 4), the Propofol package inserts from two drug manufactures, Pfizer and Sagent, were reviewed. The Propofol package insert indicated, "Propofol is an

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intravenous general anesthetic and sedation drug for use in the induction and maintenance of anesthesia or sedation. . .There are reports of abuse of Propofol for recreational and other improper purposes, which have resulted in fatalities and other injuries. . .inventories of Propofol should be stored and managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting". MD 4 agreed and stated, "Propofol can induce unconsciousness or sedate patients." MD 4 stated physicians need to be "qualified" to administer Propofol and be "signed off to secure airways" in accordance with the MEC (Medical Executive Committee -a committee of staff physicians). MD 4 stated Propofol should be "controlled" but is not at [Facility]. MD 4 stated, "There are many bad incidents at the [Facility]."

During an interview on 3/23/21, at 12:15 PM, with Pharmacy Tech Manager, (PTM), PTM stated Propofol has "diversion potential. . .it is secured as possible" and stored in the pharmacy, "in the same manner as controlled substances. . .in the sense it is removed and tracked" through the Pyxis. However, waste (unused portion) is not monitored or accounted for.

During an interview on 3/24/21 at 2:35 PM, with Emergency Department Physician (MD 6), MD 6 stated physicians need medical staff privileges for sedation and to use PROPOFOL. MD 6 stated he is unaware how Propofol is "handled or wasted" because the ED nurses manage it. MD 6 stated ED physicians do not have access to the Pyxis or give medications. MD 6 stated, he does not have access to the Pyxis and does not handle medications. Medications are ordered and the

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nurses give it.

During an interview on 3/24/21, at 5:25 PM, with Chief, Department of Anesthesia (MD 3), MD 3 stated, Propofol is "diverted" and not "controlled and "monitored" at [Facility].

During an interview on 3/25/21, at 8:40 AM, with Certified Registered Nurse Anesthetist (CRNA 1), CRNA 1 stated Propofol "should be controlled." In the [Facility] there is "no documented waste". Twenty ml (millimeter, volume of measurement) syringes of Propofol are thrown into large sharp container [hospital waste container for syringes needles] and anyone can pull it out, reach in, grab it." CRNA 1 stated, "too many people using and OD [overdosing]. . .available. . .not wasted. . .left on top of carts. . .easy for others to get. . .easy access".

During an interview on 3/25/21, at 2:08 PM, with Anesthesia Resident (a physician who has finished medical school and is training in a specific area or medical specialty) PGY 3 (Resident 5), Resident 5 stated. "Propofol is prone to abuse and misuse."

During an interview on 3/25/21 at 3:45 PM, with CRNA 2, CRNA 2 stated, at other hospitals he works at "Propofol is controlled'", but not at this [Facility] and staff and providers do not need to account for waste.

During an interview, on 3/29/21, at 7:05 PM, with Emergency Department Physician MD 7, MD 7 stated Propofol is a "controlled" substance and he does not know how Propofol is wasted. He stated all medications are given by the nurses. MD 7 stated, SC 1 was found in the ED public

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bathroom and during resuscitation, "needles" and "big syringes, 60 ml" of Propofol were found.

During an interview on 3/31/21, at 10:30 AM, with Emergency Department Resident PGY 2 (Resident 8), Resident 15 stated "Propofol is controlled", and the nurses obtain it from Pyxis but Resident 15 does not know how it is wasted.

During an interview on 3/31/21 at 4:20 PM, with Director of Pharmacy Services (DPS), DPS stated Propofol is not a controlled [substance]. . .is divertible and waste is not tracked". DPS stated there are "no strategies" to control use or waste of Propofol.

During an interview on 3/23/21, at 8:15 PM, with Registered Nurse (RN 3), RN 3 stated Propofol will be "left hanging and attached to the patient" for several hours during use or when it is on pause. The bottle is not secured to prevent others from accessing it. RN 3 stated, in addition to SC 1, there were three other recent discoveries in ED bathrooms of used syringes and needles found with white milky substance. . .looked like Propofol, and blood on the walls.

During an interview on 3/30/21 at 9:10 PM, RN 1, RN 1 stated Propofol can be left "hanging on the pole" for up to six hours and still connected to Patient 1. . .and could restart it if needed. The bottle is not secured to prevent others from accessing it. RN 1 stated she noticed Propofol missing, (3/4's of the bottle) from Patient 1's bottle in room 19. RN 1 stated, [SC 1], was found with the "white substances in the syringes and blood in the bathroom, and during the code we found more syringes".

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During an interview on 3/26/21, at 10:18 AM, with Security Officer (SO 1) SO 1 stated and in a report indicated "staff members found syringes with a milky white substance, alcohol wipes, and blood in the staff restroom outside of Zone 3 that night and the night prior to SC 1's death. There were concerns a "staff member was potentially using drugs in this location." SO 1 stated these incidents were not reported to security department.

5. During the Governing Board (GB) Meeting on 4/1/21, at 12:20 PM, the Chief Executive Officer (CEO) stated the GB is "responsible for the medical and quality care, and safety" of the hospital. The CEO stated the contracted staff, "abide by Policy and Procedures, contracts and medical staff [requirements]" and the Governing Body has "responsibility" of all staff and contracted staff for behavior, medical services, and safety.

During the Case Review Committee Meeting on 03/24/21, at 7 AM, the CEO stated, MD 1 "admitted to diverting" [Facility] controlled substances. The CEO stated, MD 1's diversion was a "single event," a "single provider" and does "not happen often here at this [Facility]." After reviewing random 25 charts there was "no patient harm" and "no fentanyl diversion". CEO stated, if there is an "additional problem, there's not much to investigate". CEO stated, MD 1 self-reported himself to the Well-Being Committee (a committee of five physicians and decides what is best for patient safety), and enrolled himself in the rehabilitation program. MD 1 went on a medical leave and had no further cases. CEO stated, since there was "intervention . . .don't need to suspend [MD 1]" and does not require a

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report to the Medical Board of California.

During an interview on 4/1/21, at 8:10 AM, with Chief of Staff (MD 2) a topic of discussion was about diversion, substance use, and impairment of providers. MD 2 stated, MD 1 admitted to diverting controlled substances from patients for self-use. MD 2 stated he became aware of MD 1's possible substance use disorder and diversion in July 2020. MD 2 acknowledged controlled substance audits, investigation, patient safety inquiry, or monitoring were not initiated in July 2020. In January 2020, MD 2 acknowledged more concerns arose. MD 2 stated, MD 1 took a "leave of absence", joined the Well-Being Committee, so an "investigation" for diversion and/or report to the Medical Board were not required. As for Certified Registered Nurse Anesthetist (CRNA 4), MD 2 stated, he was aware of CRNA 4's impairment and suspicion of being under the influence of substances while caring for a patient in the operating room. MD 2 stated another physician had to intervene and take over the care for the patient. MD 2 acknowledged controlled substance audits, investigation and/or patient safety inquiries, were not initiated in on CRNA 4. MD 2 stated "there was nothing to investigate, she resigned". MD 2 stated he was unaware of CRNA 7's diversion of controlled substances, criminal investigation, and charges.

During an interview on 3/29/21, at 4:05 PM, with Graduate Medical Education, (GME), Program Director Anesthesia, (MD 4), a topic of discussion was about diversion, substance use and impairment of providers. MD 4 stated, CRNA 1 spoke to him about "concerns" regarding MD 1, but "don't recall the concern". CRNA 1 submitted

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a MIDAS (occurrence reporting system) event report on 1/8/21, describing concerns of MD 1's overuse of opioids and diversion. MD 4 stated, MD 1 informed him, "He had a problem" and wanted to join "Well-Being." MD 4 stated, after MD 1 joined the Well-being Committee, it all became "confidential". MD 4 stated there were "Midas" report about CRNA 4 concerning impairment while working in the operating room. MD 4 stated he was unaware of CRNA 7's diversion of controlled substances, criminal investigation and charges. MD 4 stated, Resident 14 (a physician who finished medical school and in training in a specialized area or medical specialty) "had issues with anesthesia." MD 4 stated there were "Midas reports for residents". MD 4 stated he had no knowledge, Resident 14 overdosed while at work, was seen in the ED and had drug testing at [Facility]. MD 4 stated he was unaware of Resident 14's drug testing and "should have been informed. MD 4 acknowledged he was not aware of controlled substance audits, investigation, patient safety inquiry and/or monitoring initiated for these events for CRNA 4, CRNA 7, Resident 14, or MD 1. MD 4 stated he is not aware of any controlled substances discrepancies involving anesthesia providers.

During an interview on 3/26/21, at 11:51 AM, with Anesthesia Resident PGY 4 (Resident 7), Resident 7 stated, the pharmacy will email the resident or provider if there are any controlled substance "discrepancies." "I [Resident 7] get an email, I correct the error, but I'm not necessarily the one who made the mistake. . .the attending [supervising physician] pushed meds [medications given via a vein] during care. . .I didn't make the mistake". Resident 7 stated "No matter who pulled [removed medications from

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Pyxis], the standard for CA 1-3 [anesthesia resident training years] attendings push meds" and resident records what the attending tells the resident what to chart.

During an interview on 3/24/21, at 5:25 PM, with Chief, Department of Anesthesia (MD 3) MD 3 described how discrepancies of controlled substances are resolved at [Facility]: the pharmacy will "email, text or verbally" inform provider or resident who removed the medications from the Pyxis machine of the discrepancy. The provider or resident will "fix" the discrepancy and "correct the chart", within a week to one year, by opening the chart and placing the missing dose of medication on the intraoperative record. MD 3 stated, the electronic medical record allows entries and changes of the record anytime. The "record does not show what was changed, just the date it was re-signed". MD 3 stated providers can "write addendums" that are time stamped, of what and why was changed in the medical record, but "it is not done, too much trouble". MD 3 stated there is no "reporting or tracking", "no investigations", "no monitoring" regarding how many controlled medication discrepancies must be "fixed" per provider. With this method the anesthesia department is "99% correct for controlled substances" reconciliation.

During an interview on 3/31/21, at 4:20 PM, with Director of Pharmacy Services (DPS), DPS stated, MD 1 admitted to diverting fentanyl (a narcotic pain medication) from patients for self-use from May 2020 to 1/20/21. DPS stated there was an audit on fentanyl. DPS stated, the pharmacy department "did not do a deep dive on other anesthesiologists. . .looked. . .no discrepancies." DPS stated he did not inquire

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about other controlled substances or Propofol (sedation medication, that is divertible) used and accessed by anesthesiologist.
DPS acknowledged medications removed from the Pyxis by residents on MD 1's and other anesthesiologists behalf were not investigated or audited. DPS stated, the pharmacy found "no discrepancies" for CRNA 7 or MD 1. DPS stated if there is a controlled substance discrepancy, "documentation was cleaned-up by anesthesia." that is, "missing, is not documented". The pharmacy "will ask physician to correct [it]".

6. During a review of Patent 1' s Emergency Documentation, dated 12/21/20, the ED Notes indicated, "At 7:01 PM, Patient 1 was "critically ill. . ."in distress." Patient 1 was a full code. At 10:37 PM, Patient 1 "had a wide complex tachycardia [life threatening malfunction of heart beats] on the monitor and lost pulses and CPR (cardiopulmonary resuscitation, life sustain efforts) were initiated. . .ROSC [return of spontaneous circulation] was achieved." At 11:00 PM, Patient 1 was evaluated by an Intensive Care Unit (ICU) PGY 1 Resident 9 (physician in training)-- vitals temperature 36.6 centigrade (normal 36.1), heart rate 104 on the monitor, respiratory rate 22, blood pressure 14/81, SP02 [oxygen saturation] 90%. Resident 1 documented, Patient 1 had a successful resuscitation efforts and ROSC (return of spontaneous circulation) and was on a ventilator. On 12/22/21, at 12:35 AM, the ED Notes indicated Patient 1's vital signs were: blood pressure of 122/91, heart rate 104, respiratory rate 22 and ventilator in use. At 12:41 AM, the ED Notes indicated Patient 1's heart rhythm was "A Fib [atrial fibrillation, an irregular rhythm], a heart rate of 70 beats per minute, and BBB (bundle

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branch block, an abnormal heart beat path in the heart). Patient 1 was waiting for ED transfer orders, so he could be moved to the ICU for continuation of care. There was no documentation of an assessment, status change, updated laboratory values from ED admission, orders for change of full code to "comfort care" status and withdrawal of medical care, communication with the family and/or communication documented with other providers by ED Physician (MD 5), Resident 1 or ED nursing.

During a concurrent interview and record review on 3/23/21, at 4:35 PM, Patient 1's Emergency Documentation was reviewed. The ED Notes indicated, "Between 12:42 a.m. and 1:41 a.m. Patient 1, who was full code, intubated, on a ventilator, and waiting to be admitted to the ICU, status was changed to "comfort care" or reasons to withdrawal of medical care. Neither, MD 1 or Resident 1 documented an assessment to determine Patient 1's viability or signs of life. There was no documentation of vital signs or assessment of Patient 1 by MD 5, Resident 1, RT 1 or RN 1. There was no documentation of vital signs, temperature, cardiac monitoring, oxygen delivery, ventilator use, ECG [Electrocardiogram], reflexes, apnea [breathing that stops from any cause] test, examine the heart, lungs and nervous systems, or normal laboratory values. There were no documented orders, POLST (Physician Order for Life Sustaining Treatment-life directives stating one's wishes for full resuscitation, partial resuscitation, no code, or natural death. It must be signed by the patient and/or patient representative, and physician) form, neurology (physician who evaluates the brain and spinal cord) consult or palliative care

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(provides relief from pain and symptoms) consult. MD 5 verified the findings.

During an interview on 3/23/21, at 8:35 PM, and concurrent chart review, with ED Resident PGY 1 (Resident 1), Resident 1 confirmed Patient 1 was a "full code", intubated, on a ventilator, and waiting to be admitted to the ICU. Resident 1 stated, he decided Patient 1 had a poor outcome and "put him on comfort care." Resident 1 acknowledged he did not speak with the family or patient representative regarding changing Patient 1's full code status, nor were there written orders. Resident 1 stated he "believes" MD 5 spoke with family about "comfort care" and "patient status". Resident 1 did not speak with MD 5 regarding Patient 1's code status, and he did not document any communications with MD 5, the supervising physician. Resident 1 did not complete an assessment to determine Patient 1's viability or signs of life or reasons to withdrawal of medical care. Resident 1 did not obtain vital signs, temperature, heart monitoring, ECG, reflexes, apnea test, examine the heart, lungs and nervous systems or obtain normal laboratory values.

During an interview on 3/23/21, at 3:46 PM, with Emergency Department Physician (MD 5), MD 5 stated, Resident 1 gave a "verbal order for fentanyl (narcotic pain medication) 100 mcg (microgram, a unit of measure)." MD 5 stated he "recalls" Patient 1's wishes to be a "full code", but "can't recall" how the "full code" was changed to "comfort care". MD 5 stated Resident 1 was "taking care of Patient 1."

During an interview on 3/23/21, at 8:35 PM, with Resident 1, Resident 1 stated, [MD 5] ordered the fentanyl at 1:22 a.m. and did "not recall" when it

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was given.

During a review of Patient 1's Emergency Documentation, dated 12/22/20, the ED Notes indicated, Patient 1 was extubated (breathing rube removed) at 1:43 AM. There was no documentation of vital signs, temperature, cardiac monitoring, oxygen delivery, ventilator use, ECG, reflexes, apnea test, examine the heart, lungs and nervous systems, or normal laboratory values. At 1:53 AM, Emergency Department Physician (MD 7) was assigned to take over the care of Patient 1 from MD 5. The ED Notes indicated MD 5 placed Patient 1 on "comfort care status. . .administering fentanyl 100 mcg IV [intravenously, via a vein]. . .withdrawing ETT [removing breathing tube], mechanical ventilation [breathing machine] and vasopressor support [medications to help maintain blood pressure and heart rate]." The ED notes indicated, "MD 7 was notified by patient's nurse that he [Patient 1] had lost his pulse and had no documented blood pressure". No interventions were taken to persevere life. MD 7 pronounced death of Patient 1 at 1:53 AM."

During an interview on 3/29/21, at 7:05 PM, with MD 7, MD 7 stated he did not know how Patient 1 went from a full code, with successful ROSC, and pending ICU admission to "comfort care" and withdrawal of medical care. MD 7 acknowledged he "did not read the chart" or "consult with MD 18 regarding Patient 1's status, code status, and patient care." MD 7 stated MD 5 changed Patient 1's status to "comfort care." MD 7 stated he took his word. . . trusted him. . .to tell me what happened". MD 7 stated, he "wrote what he [MD 5] told me . . .did what MD 5 told me to do." MD 7 acknowledged, he pronounced the death of

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Patient 1, and he did not complete an assessment to determine Patient 1's viability or signs of life. MD 7 acknowledged he did not obtain vital signs, temperature, cardiac rhythm strip, reflexes, EEG test, and apnea test, examine the heart, lungs and nervous systems or obtain normal laboratory values.

During an interview on 3/29/21, at 6:17 PM, with Critical Care Physician (MD 18), MD 18 stated, Patient 1 was a full code and intubated, had a successful ROSC, and was pending ICU admission. MD 18 stated the Resident (1) notified him that Patient 1's Code status was changed to "comfort care" and withdrawal of medical care, and would no longer need ICU admission. MD 18 stated he "did not have answers" and there was no documentation why the status was changed by the Resident (1). MD 18 stated the ICU team consulted on Patient 1 and was never transferred to the ICU. MD 18 stated the ICU team was not involved with or present at Patient 1's death. MD 18 stated if a patient is a "full code "and there is consideration for "comfort care" and withdrawal of medical care, there are "protocols": neurology protocols-- "brain death. . .[absence of] reflexes. . .EEG [brain activity scan] of the brain"; "respiratory protocols" for instance increased carbon dioxide, lack of breathing; laboratory tests need to be normal and negative for drugs; obtain a Palliative Care consult for "comfort care. . .they make the decision and discuss with family" comfort care and withdrawal of medical care. MD 18 stated he "would not have made any decision about comfort care on a full code". MD 18 stated, he did not sign-off that Patient 1 was not a corner's case. MD 18 stated he does not have privileges for palliative care, anesthesia, hospice, neurology that are needed to withdrawal medical

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care. MD 18 stated, "he [Patient 1] wasn't an ICU patient. . .asked to write the death summary. . .I'm new and didn't want to cause problems. . .so I did it". The chart reflected a "death summary" written at 6:37 AM, by Resident 4 and co-signed by MD 18.

During an interview on 3/23/21, at 9:52 AM, with Surgery Resident PGY 1 (Resident 4), Resident 4 stated, the process for determining brain death, for example a "brain scan. . .brain stem reflexes. . .EEG [brain activity scan]. . .neurology consult (physician specialist who evaluated the nervous system)." Resident 4 stated, she would "wait till cleared" and exam completed to determine death of a patient.

During an interview on 3/23/21, at 8:35 PM, with Respiratory Therapist (RT 1), RT 1 stated the physician had made Patient 1 "comfort care and asked me to remove the breathing tube". RT 1 stated based on a "verbal order", she "removed" Patient 1's breathing tube. RT 1 acknowledged, she did not have a physician order.

During an interview on 3/24/21, at 2:35 PM, with Emergency Department Physician (MD 6), MD 6 stated, ED physicians "talk about end of life and 'comfort care'. . .reading from the POLST form. . .no written process after CPR [cardiopulmonary resuscitation, life-saving efforts]. . .if ROSC [return to spontaneous circulation after CPR], no situation to go to comfort care" or withdrawal of medical care for a patient. MD 6 stated brain death is determined in the ICU and "never in the ED".

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Guidelines for

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805.01 (CA Business Professional Code", (MS 33) dated, 6/26/18, the P&P indicated, "Before reporting actions under 805 and to the applicable licensing board, certain final decisions or recommendations of the Medical Executive Committee covered by this policy must satisfy four elements 1. Deny, terminate of restrict the clinical privileges of a practitioner; 2. Recommendation by the Medical Executive Committee; 3. Following a formal investigation and 4. MECs that any of the following acts have occurred. For example, incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or herself, any controlled substance."

During a review of the hospital's policy and procedure (P&P) titled, "Medication Administration" (PC 19), dated 6/19/19, the P&P indicated, "The accuracy of controlled substance transactions will be verified by performing a discrepancy report at the change of each shift in the setting which are open on a 24 hour basis. . .Timely discrepancy investigation and resolution is necessary to comply with Federal and State theft/loss reporting requirements".

During a review of the hospital's policy and policy and procedure (P&P) titled, "Pyxis Anesthesia System (PAS)", (RX 7.50.0), dated 2/9/21, the P&P indicated "To provide secure and identifiable access to medications. . .Waste transactions must be created in PAS any time a controlled substance is removed from PAS but not completely administered. This activity must be performed no later than the end of the case. . .The Chief of Anesthesiology (or designee) and

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Director Pharmacy (or designee) will be informed of any inconsistencies so that appropriate action(s) can be taken. . .Anesthesia Providers are responsible for ensuring that physical counts agree with the system's internal count. . .CS [controlled substance] discrepancies must be resolved as soon as possible, the timeframe for discrepancy resolution should be no later than 24 hours from the time of discovery. . .The individual responsible for creating a discrepancy [removed medication for PAS] is ultimately responsible for its".

During a review of the hospital's policy and procedure (P&P) titled, "Medication: Narcotics", (PC 67), dated 8/23/16, the P&P indicated, "All controlled medications "will be accounted for with appropriate documentation. Timely discrepancy resolution is necessary to comply with Federal and State theft/loss reporting requirements. . .discrepancies are to resolved no later than 24 hours after discovery. . .If a discrepancy cannot be satisfactorily resolved within 72 hours, the CNO [Chief Nursing Officer], VP [Vice President] of Human Resources, Risk Management and the DOP [Director of Pharmacy] will initiate appropriate action. (See Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse (AP 110)."

During a review of the hospital's policy and procedure (P&P) titled, "Dangerous Drugs: Theft/Loss", (KDEP 11), date 6/19/19, the P&P indicated and "outlined the proper procedure in the case of theft/loss of controlled substance, chemicals listed in the Department of Justice Manual ("List 1 Chemicals, substances regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other

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| A 021 | Continued From page 35<br>dangerous drugs. . .Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft. . .loss in transit. . .Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and/or other law enforcement agency. 6. California Department of Public Health."<br><br>During a review of the California State and Federal Regulations, titled, "Uniform Determination of Death Act" UDDA the regulations indicated, "determine death of patient--, approved for the United States in 1981 when an individual may legally be declared dead. . .and Health Safety code State of California Chapt 3 section 7180 et., (a) An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in | A 021 | | |

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accordance with accepted medical standards. . . (c) This article may be cited as the Uniform Determination of Death Act. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=7180. Accessed 4/24/2021.

During a review of the Uniform Determination of Death Act (UDDA), the regulation indicated, "It is a "model state law that was approved for the United States in 1981 by the National Conference of Commissioners on Uniform State Laws, in cooperation with the American Medical Association, the American Bar Association, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research". The act has since been adopted by most US states and is intended "to provide a comprehensive and medically sound basis for determining death in all situations".[1] Brain death is a different condition than persistent vegetative state. If the doctors believe there is little to no chance of recovery, then family and loved ones may seek a court order to remove the patient from life support (which is not necessary if the patient or someone with power of attorney has signed a "do not resuscitate," or DNR, order). In the absence of a court order or a DNR, the hospital is obligated to keep the patient alive through artificial means until further notice. Someone who's medically declared brain dead -- meaning there is zero brain activity -- is legally considered dead. A patient considered "highly unlikely" to live beyond a vegetative state, after having gone through rigorous testing, may be diagnosed as being in a persistent vegetative state. https://healthcare.findlaw.com/patient-rights/brain-death-vs-persistent-vegetative-state-what-is-the-l

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egal-difference.html. Accessed 4/24/2021.

During a review of the California State Regulations, titled, "Business and Professional Code BCP) 805.01," the regulation indicated, "As used in this section, the following terms have the following definitions: (1) Agency has the same meaning as defined in Section 805. (2) Formal investigation means an investigation performed by a peer review body based on an allegation that any of the acts listed in paragraphs (1) to (4), inclusive, of subdivision (b) occurred. (3) Licentiate has the same meaning as defined in Section 805. (4) Peer review body has the same meaning as defined in Section 805. (b) The chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic shall file a report with the relevant agency within 15 days after a peer review body makes a final decision or recommendation regarding the disciplinary action, as specified in subdivision (b) of Section 805, resulting in a final proposed action to be taken against a licentiate based on the peer review bodys determination, following formal investigation of the licentiate, that any of the acts listed in paragraphs (1) to (4), inclusive, may have occurred, regardless of whether a hearing is held pursuant to Section 809.2. The licentiate shall receive a notice of the proposed action as set forth in Section 809.1, which shall also include a notice advising the licentiate of the right to submit additional explanatory or exculpatory statements electronically or otherwise. (1) Incompetence, or gross or repeated deviation from the standard of care involving death or serious bodily injury to one or more patients, to

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the extent or in such a manner as to be dangerous or injurious to any person or to the public. This paragraph shall not be construed to affect or require the imposition of immediate suspension pursuant to Section 809.5. (2) The use of, or prescribing for or administering to himself or herself, any controlled substance; or the use of any dangerous drug, as defined in Section 4022, or of alcoholic beverages, to the extent or in such a manner as to be dangerous or injurious to the licentiate, any other person, or the public, or to the extent that such use impairs the ability of the licentiate to practice safely.

During a review of the Federal Drug Administration labeling requirement, FDA indicated, "inventories of DIPRIVAN (Propofol) should be stored and managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting". The FDA further indicated in the labeling information that Diprivan self-administration of DIPRIVAN Injectable Emulsion by health care professionals have been reported, including some fatalities. DIPRIVAN Injectable Emulsion should be managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting". https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019627s066lbl.pdf https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/19627S35LBL.pdf. Accessed on 4/10/2021.

During a review of two drug manufacturer package inserts (medication information) about "Propofol (Diprivan) Injectable Emulsions" both used by the hospital, on 3/24/21, at 4 PM, the

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inserts indicated, Manufacturer 1 package insert indicated, "Propofol is an intravenous general anesthetic and sedation drug for use in the induction and maintenance of anesthesia or sedation. . .There are reports of the abuse of Propofol for recreational and other improper purposes, which have resulted on fatalities and other injuries. . .inventories of Propofol "should be stored and managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting." Manufacturer 2 package insert indicated, "Propofol is an intravenous general anesthetic and sedation drug for use in the induction and maintenance of anesthesia or sedation. . .There are reports of the abuse of Propofol for recreational and other improper purposes, which have resulted on fatalities and other injuries. . .inventories of Propofol "should be stored and managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting".

During a review of the California State Regulations, Health and Safety Code (HSC), 11153, the regulation Indicated "A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course". https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=11153. Accessed 4/24/2021.

During a review of Federal Regulation for Controlled Substance Title 21, the regulation Section 863 indicated, "It is "unlawful for any person to sell or offer for sale drug paraphernalia; to use the mails or any other facility of interstate

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commerce to transport drug paraphernalia; or to import or export drug paraphernalia. . .(d) "Drug paraphernalia" defined the term "drug paraphernalia" means any equipment, product, or material of any kind which is primarily intended or designed for use". https://www.govinfo.gov/content/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap13-subchapI-partD-sec863.pdf. Accessed 4/24/2021.

During a review of the Federal Regulations for Controlled Substances, Title 21, Section 205.50, indicated, "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution record by wholesale drug distributors and their officers, agents, representatives, and employees." https://www.govinfo.gov/content/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap13-subchapI-partD-sec863.pdf. Accessed 4/24/2021.

During a review of the California State Regulations, Health and Safety Code, 11364 (a), indicated "It is illegal to possess drug paraphernalia. This is defined as any device, instrument or paraphernalia used for unlawfully injecting or smoking a controlled substance". https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=11364. Accessed 4/24/2021.

During a review of the California State Regulations, Business and Professional Code 4104, indicated "Reporting requirements, self-use of dangerous drugs). (a)Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or discovered or known to be

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chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (b)Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy".
https://codes.findlaw.com/ca/business-and-professions-code/bpc-sect-4104.html. Accessed 4/24/2021.

During a review of the California State Regulations, Health and Safety Code Section 11100, indicated "(1) any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian. (2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients. (3)?Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department. . . (5)?A state-licensed health care facility that administers or furnishes a substance to its patients. . .(8)?Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste. (f)(1)?Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who

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knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment." https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=HSC&division=10.&title=&part=&chapter=&article. Accessed 4/23/2021.

During a review of the California State Regulations, Title CCR, Division 17. 1711. § 1711. Quality Assurance Programs indicated, " (a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors."

During a review of Federal Regulations for Controlled Substances, Title 21 Section, 1304.11, indicated "Inventory requirements, indicated "(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances". https://www.deadiversion.usdoj.gov/21cfr. Accessed 4/20/2021.

During a review of Federal Regulations for Controlled Substances, Title 21 Section 1317.0, indicated "Rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against

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| A 021 | Continued From page 43<br>the diversion of controlled substances". https://www.deadiversion.usdoj.gov/21cfr. Accessed 4/20/2021. | A 021 | | |
| A 043 | GOVERNING BODY<br>CFR(s): 482.12<br><br>There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ...<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to ensure the Governing Body was responsible for the conduct of the hospital operations and carried out the responsibilites and the functions specific to the governing body as evidenced by:<br><br>1. The Governing Body (GB) failed to discipline, cancel, or suspend the privileges (right to practice) of three of three sampled Providers (Chief of Anesthesia [MD, specialty practice of medicine where medications are provided for temporary loss of sensation or awareness, such as for surgery] 1, Certified Registered Nurse Anesthetists [CRNA, Advance Practice Provider with specialty training in anesthesia] 4, and CRNA 7) with substance use disorder and/or refused a screening exam, which was consistent with established hospital policy and bylaws. This failure had the potential to result in patients' health and safety to be in danger when placed under the care of impaired providers. (Refer to A0046) | A 043 | | |

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| A 043 | Continued From page 44<br><br>2. The Governing Body failed to ensure Medical staff followed the facility policy and procedures for chain of custody of medications and reporting of potential substance abuse. This failure resulted in drug diversion. (Refer to A0047)<br><br>3. The Governing Body failed to ensure four of four emergency department physicians ([Medical Doctor] MD 5, MD 6, MD 7, and MD 14) met contractual agreements for reappointments and /or continued membership. This failure resulted in MD 5, MD 6, MD 7, and MD 14 providing emergency medical care without the appropriate certifications required for the job. (Refer to A0050).<br><br>4. The Medical Staff failed to ensure the Medical Executive Committee (MEC is a team of physicians that monitor and review physician behavior, conduct and patient safety) had the authority to oversee the professional conduct of the Chair, Department of Anesthesia (MD 1) and patient safety of the medical staff in providing safe and quality medical care for 311 hospital patients, as allowed by the medical staff bylaws, contract agreement, and policies. This failure resulted in the medical staff office making decisions about the professional behavior of MD 1 without MEC input review, which potentially compromised the health and safety of the patients when impaired Providers are allowed to continue to render medical care. (Refer to A0053).<br><br>5. The Medical Staff failed to refer unknown cause of death to coroner's office, secure medication, syringes and needles in the emergency department (ED). These failures | A 043 | | |

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| A 043 | Continued From page 45<br>resulted in unauthorized staff accessing dangerous medications (Refer to A0083)<br><br>7. The Governing Body failed to ensure ED Staff were informed of the duties, responsibilities, and restrictions for a contract staff, Scribe (SC- a person who performs patient documentation and clerical tasks on behalf of a physician) 1. This failure resulted in SC 1's access to needles, syringes, and dangerous medication and subsequent death. (Refer to A084)<br><br>The cumulative effects of these systemic failures had the potential to negatively impact the safety and quality of care, treatment, and services of the patients, staff, and the public. | A 043 | | |
| A 046 | MEDICAL STAFF - APPOINTMENTS<br>CFR(s): 482.12(a)(2)<br><br>[The governing body must] appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Governing Body (GB) failed to discipline, cancel, or suspend the privileges (right to practice) of three of three sampled Providers (Chief of Anesthesia [MD, specialty practice of medicine where medications are provided for temporary loss of sensation or awareness, such as for surgery] 1, Certified Registered Nurse Anesthetists [CRNA, Advance Practice Provider with specialty training in anesthesia] 4, and CRNA 7) with substance use disorder and/or refused a screening exam, which was consistent with established hospital policy and bylaws. This | A 046 | | |

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failure had the potential to result in patients' health and safety to be in danger when placed under the care of impaired providers.

Findings:

During an interview, on 3/29/21, at 4:05 PM, with Graduate Medical Education Program Director, Anesthesia (MD 4), MD 4 stated, after MD 1 joined the Well-Being Committee [assists physicians with matters related to prevention of impairment and maintenance of health, with particular attention to substance abuse or addiction, mental illness, or behavior], it all became confidential and any action regarding Peer Review Committee (PRC) review, Medical Executive Committee (MEC) review, and the investigation stopped. MD 4 stated, MD 2 did not refer MD 1 to Peer Review, MEC, or notify the GB of concerns about MD 1 diverting controlled substances. MD 4 stated, CRNA 4 had a "problem with addiction and resigned," and the "MIDAS" [reporting system for healthcare workers to report concerns] report filed about CRNA 4 concerning impairment while working in the operating room. MD 4 stated, if medical staff did not believe an adverse event occurred, the MIDAS report would not reach root cause analysis (RCA-process to identify issues/concerns regarding patient safety) stage, the PRC, or the MEC and the MIDAS Report would be closed, no further action required.

During a concurrent interview and record review, on 3/31/21, at 11 AM, with Director of Medical Staff (DMS), the Providers' Credential (qualification) and Employment Files for MD 1, CRNA 4, and CRNA 7 were reviewed. The credential files for MD 1, CRNA 7, and CRNA 4

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indicated, these Providers did not adhere to ethics of profession related to substance use disorder, and/or diversion, and their privileges were not sanctioned, and/or suspended. DMS verified the findings.

During a concurrent interview and record review on 3/31/21, at 12 PM, with DMS, MD 1's employment file was reviewed. MD 1's employment file did not indicate any sanction (disciplinary action) or suspension from the MEC or the Governing Board. DMS stated, MD 1 "confessed to diversion" of controlled substance, self-referred to Well-Being Committee and took a leave of absence. DMS stated, MD 1 was not subject to investigation, suspension, or sanction of his privileges, and he was not referred to MEC since he self-referred to the Well-Being Committee. DMS stated, MEC did not take disciplinary action and the medical staff was not obligated to notify the Medical Board. DMS stated, MD 1's employment file did not contain a report to the California Medical Board regarding MD 1's diversion.

During a concurrent interview and record review on 3/31/21, at 11 AM, with DMS, and Medical Staff Manager (MSM), CRNA 7's employment file was reviewed. DMS stated, CRNA 7's file contained a letter from the [Facility] Department of Pharmacy Services (DPS), regarding an audit for Ketamine (a strong pain medication and tranquilizer) and Propofol (a strong sedation medication given into a vein. High doses or rapid administration may stop breathing). The letter indicated DPS had not completed the Propofol audit. The letter indicated the Pharmacy had not purchased the ketamine and Propofol found at the "scene" of the overdose death. DMS stated,

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| A 046 | Continued From page 48<br>the Director of Risk Management (DRM) was unable to locate the MIDAS (occurrence reporting system) report regarding CRNA 7. DMS was unable to provide any comments, suspension, or disciplinary action from the Medical Executive Committee (MEC) or Governing Body. DMS was unable to provide an RCA. DMS stated, a MIDAS report must be generated for a patient safety issue or provider behavior concern to reach MEC and Peer Review Committee (PRC). DMS stated, the MIDAS report would be referred to the medical staff office if there was a patient safety issue or provider behavior concern. DMS stated, after review, the medical staff office might refer the provider to the MEC or PRC. DMS stated, CRNA 7's file was not updated after the DPS investigation or the criminal investigation. DMS stated, CRNA 7's file does not contain any comments that preclude her from being reappointed. DMS was unable to provide reviews from PRC, MEC, or Governing Body for CRNA 7.<br><br>During a record review with DMS and MSM, on 3/31/21, at 11:15 AM, CRNA 4's employment file was reviewed. CRNA 4's employment file indicated the following:<br>Several documents, dated 2008 through 2013, from the Alabama Board of Nursing regarding disciplinary action and enrollment in the Addiction Recovery Program, Birmingham Alabama.<br>On event date 11/26/17, a MIDAS report, indicated a "serious safety event, moderate temporary harm." CRNA 4 was unable to manage a "respiratory crisis." CRNA 4 removed from clinical duties because of "suspicion of impairment." CRNA 4 resigned when asked to provide a urine drug test.<br>On 6/29/16, Letter to CRNA 4 from Chief Medical Officer indicated, "hereby notifies immediate | A 046 | | |

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administrative suspension of membership and all privileges" at [Different Facility], and CRNA 4 will be referred to the Medical Executive Committee who will "make a recommendation to the Governing Board."
On 1/28/19, letter informed CRNA 4 granted privileges at [Facility] for two years without modifications.
DMS stated, after suspicion of impairment, CRNA 4 refused to submit a drug screen and resigned on 11/27/19.
On 12/3/19, Referral to the Board of Registered Nursing, California, by Chief, Department of Anesthesia (MD 1), indicated CRNA 4 had not intubated a patient correctly, had failed to identify the issue and resigned prior to completing the agreed to drug test.
DMS was unable to provide documented evidence of an RCA for the event on 11/27/19.
DMS stated, for a patient safety issue or provider behavior concern to reach MEC and PCR, a MIDAS report would be reviewed by the Medical Staff Office, and the medical staff office would determine if the MIDAS report moves forward to MEC or PRC.

During a concurrent interview and record review on 3/31/21, at 12:15 PM, with DMS, the P&P for "Disciplinary Action to Occur" was reviewed. The P&P indicated, providers must be referred to the MEC for review and investigation. DMS stated, MD 1 must follow the Medical Staff (MS) policies: "Peer Review Process," "Impaired Provider Policy," "Code of Conduct for Medical Staff & Advanced Practice Providers," and "Medical Staff Well-Being Committee." The following policy and procedures indicated, they were based on federal and/or state regulations and/or specifically mentioned providers or physicians included:

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"Suspected Illegal Substances," "Dangerous Drugs: Theft/Loss," "Medications: Narcotics," "Drug Free work Place and Drug/Alcohol Testing," Requirements for Contracting outside Service Provider," and more. DMS stated, they "do not apply" to physicians and reiterated they (policies and procedures) must say Medical Staff in the policy number to be valid.

During an interview on 4/1/21, at 8:10 AM, with the Chief of Staff (MD 2), MD 2 stated, MD 1's overuse and diversion of controlled substance came to his "attention in July 2020" on "separate occasions" from providers, and resurfaced at the beginning of January 2021. MD 2 stated, he did not ask MD 1 specific questions because he "had a good idea what was going on" with fentanyl (narcotic pain medication) and midazolam (sedation medication). MD 2 stated, MD 1 "admitted" to controlled substance theft, diversion, and impairment. MD 2 stated, "I determined no problem" identified, and was "satisfied." MD 2 did not refer the MIDAS reports filed for event dates 7/22/20, 1/8/21, and 1/20/21 to PRC, MEC, or GB and the reports were "closed" by Medical Staff Office. MD 2 stated, he did not initiate controlled substance audits, investigation, or monitoring for MD 1 in July 2020 or January 2021. MD 2 stated, he was aware of CRNA 4's impairment and suspicion of being under the influence of controlled substances. MD 2 stated, CRNA 4 refused to submit to a drug test. MD 2 stated, he submitted a complaint to the Board of Nursing, California for patient safety concerns and suspicion of impairment. MD 2 stated, Well-Being was not offered to CRNA 4. MD 2 stated, CRNA 4 was not referred to PCR or MEC for review or action. MD 2 stated, "There was nothing to investigate, she resigned." MD 2

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stated, he was unaware of CRNA 7's diversion of controlled substances, criminal investigation, and charges. MD 2 stated, he was aware of the death of Scribe (SC 1), and understood, "he went to the bathroom, injected himself, later found, and died." MD 2 stated, the Governing Body "gives Director of Medical Staff (DMS) the authority as medical staff director" to manage medical staff, and she "runs the show," and "DMS handles all of it."

During an interview at the Governing Body (GB) meeting, on 4/1/21 at 12 PM, the Chief Executive Officer (CEO) stated, the GB was "responsible for medical and quality care and safety" of patients. The CEO stated, Chief of Anesthesia (MD 1) "admitted to diversion and impairment from May 2020 to January 1/20/21." The CEO stated, MD 1 "self-referred to the Well-Being Committee and voluntarily took a leave of absence." The CEO stated, MD 1 did not "need to do a drug test" or "be suspended" because once in Well-Being things are taken care of. The CEO stated, since MD 1's "behavior did not pose a risk to patients," "didn't prevent him from working" and MD 1 was "not a danger to patients," the Impaired Provider Policy and Code of Conduct did not apply. CEO stated, MD 1's diversion and impairment was not at a "disciplinary level issue." CEO stated, it was not necessary to refer MD 1 to the licensing agency. The CEO stated, he did not request the MEC (Medical Executive Committee) to investigate nor disciplinary action by the MEC, so the reporting guidelines for "805 [required report to the Medical Board of California]" did not apply to MD 1. CEO stated, the MEC was made aware of MD 1's MIDAS reports and diversion for the "first time" at the 3/31/21 MEC meeting.

During a concurrent interview and record review

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| A 046 | Continued From page 52<br>on 4/1/21, at 12:15 PM, with the CEO, the P&P titled, "Impaired Provider Policy," dated 5/31/18, was reviewed. The Impaired Provider Policy indicated, "use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and may endanger the individual, his or her co-workers, patients and public ...Whenever a hospital staff members observes evidence of possible impairment by a member of the medical staff or APP [Advanced Practice Provider], while on hospital premises, the staff member shall immediately inform his or her supervisor who shall inform the CEO or representative ...The Chief of Staff or designee shall promptly conduct or supervise the administration of a Screening Physical Exam of the practitioner ...[and] ask the suspect practitioner to agree to a drug test or alcohol or other testing ...Any violation of this policy shall require testing." The CEO stated, "[MD 1] did not 'violate' any of [Facility] policies."<br><br>During a review of physician contract agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department," dated 8/20/20, the contract agreement indicated, Medical Group shall and shall require all Medical Group Personnel to: provide services under this Agreement in accordance with appropriate standards of clinical practice, all applicable federal and state laws and regulations, all applicable rules in regulations of the Medical Board of California, and the Standards of the American Board of Emergency Medicine ...Comply with all applicable medical staff bylaws, rules, regulations, policies and procedures of the [Facility], including code of conduct." | A 046 | | |

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During a record review the hospital's policy and procedure (P&P) titled, "Code of Conduct for Medical Staff & Advanced Practice Providers," dated 7/17/18, the P&P indicated, "The safeguarding of patient care and safety is paramount, and the Medical Staff will enforce this policy with disciplinary measures whenever necessary."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Well-Being Committee" (MS 02), dated 6/26/17, the P&P indicated, the "responsibility of the Well-Being Committee is advisory in nature and not a substitute for personal physician of a disciplinary body ...It will report to the MEC and to the physician in question ...Practitioners who develop a physical/mental impairment are required to 'self-report' to the chief of staff /designee. The practitioner agrees to notify the chief of staff/designee immediately in writing upon learning that he/she has developed substance abuse, mental or physical illness, or sustained any injury which could have an effect on the exercise of his/her clinical privileges ...any person, practitioner or employee, suspecting a practitioner of being impaired must imitate a report to the Well-Being Committee."

During a review of the hospital's policy and procedure (P&P) titled, "Document #5177: Physician Well-Being Committee Guidelines" California Medical Association, dated 1/2020, the P&P indicated, create and operate a committee which assists physicians with matters related to prevention of impairment and maintenance of health, with particular attention to substance abuse or addiction, mental illness, or behavior. . A

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general summary of its actions should be reported to the Medical Executive Committee and/or other organizational governing body at least quarterly. The law requires that, under specified circumstances, reports must be made of physicians to the Medical Board and/or National Practitioner Data Bank. When such instances arise, the reporting responsibility should vest [assign] in the hospital Medical Executive Committee or equivalent governing body. Well-Being Committee should serve only as an advisory and monitoring body, conducting inquiries and evaluations, and making reports to the governing committee as necessary. The Committee is charged to provide support and advocacy for physicians, and should not assume responsibility to report to government agencies or the medical staff committees responsible for credentialing, corrective action and other disciplinary matters ..."

During a review of the hospital's policy and procedure (P&P) titled, "Impaired Provider Policy" (MS 40), dated 5/31/18, the P&P indicated, "substance abuse can adversely impact patient care and workplace safety. Use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and Advance Practice Providers (APP, include CRNAs, NPs, Pas), to provide services and may endanger the individual, his or her co-workers, patients and public ...Whenever a hospital staff member observes evidence of possible impairment by a member of the medical staff or APP, while on hospital premises, the staff member shall immediately inform his or her supervisor who shall inform the CEO or representative ...The Chief of Staff or designee shall promptly conduct or supervise the administration of a Screening

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Physical Exam of the practitioner ...[and] ask the suspect practitioner to agree to a drug test or alcohol or other testing ...Any violation of this policy shall require testing. "

During a review of the hospital policy and procedure (P&P) titled, "Code of Conduct for Medical Staff & Advanced Practice Providers" (MS 47), dated 1/30/19, the P&P indicated, "Practitioners have a responsibility for the welfare of their patients ...The safeguarding of patient care and safety is paramount, and the Medical Staff will enforce this policy with disciplinary measures whenever necessary."

During a review of the physician contract agreement titled, "[Faculty] Exclusive Professional Services Agreement: Regarding the Services of Anesthesiology," dated 10/1/20, the physician contract agreement indicated, "At all times while this agreement in in effect, the CEO or CNO [Chief Nursing Officer] of the [Facility] have the right to request removal in writing with specification of cause, of any provider from privileges of the Services hereunder for reasons related to clinical performance or failure to comply with this Agreement or with the polices, bylaws, rules, regulations or code of conduct of the [Facility] or the Medical Staff ...All services shall be provided in accordance with all applicable laws regulations, accreditation requirements, and Medical Staff Bylaws and Standards. Professional Standards. Medical Group and its Providers shall perform their duties under this agreement in accordance with the rules of ethics of the medical profession and, in the case of CRNAs, the nursing profession ... in accordance with the appropriated standard of care for their respective professions and specialties including the

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guidelines of the American Society of Anesthesiologist and the Medical Staff Bylaws ...Compliance with laws. Medical Group shall perform all services under this Agreement in accordance with any and all requirements and accreditation standards applicable to the [Facility] and service ..."

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Guidelines for 805.01 (CA Business Professional Code", (MS 33), dated 6/26/18, the P&P indicated, " Before reporting actions under 805 and to the applicable licensing board, certain final decisions or recommendations of the Medical Executive Committee covered by this policy must satisfy four elements 1. Deny, terminate of restrict the clinical privileges of a practitioner; 2. Recommendation by the Medical Executive Committee; 3. Following a formal investigation and 4. MECs that any of the following acts have occurred. For example, incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or herself, any controlled substance; repeated acts of clearly excessive prescribing; or sexual misconduct with one or more patients."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated approved 12/21/2020, the Medical Bylaws indicated the "Factors for Evaluation which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, and safely, competently perform clinical privileges, and commitment to quality care...any changes in the practitioner's ability to

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safely and completely exercise privileges or perform the duties and responsibilities of appointment because of health issues, including, but not limited to, impairment due to addiction, alcohol use, or other similar issue (all of which shall be referred for review under the Impaired Provider Policy); to immediately submit to an appropriate evaluation, which may include diagnostic testing (such as blood and/or urine)...Whenever a serious question has been raised regarding: the clinical competence or clinical practice of any member of the Medical Staff, including care, treatment to management of a patient or patients; the safety or proper care being provided to patients; conduct by any staff member considered lower than the standard of [Facility]. The matter may be referred to the Chief of Staff, the chair of the department, the chair of the standing committee, or the CMO [Chief Medical Officer]. The person whom the matter is referred shall conduct or arrange an inquiry which shall include the Chief of Staff to determine whether the question raised has sufficient credibility to warrant further review and, if so, shall forward it in writing to the MEC. The Chief of Staff shall update the CEO ...the Board may direct the MEC to initiate such an investigation ...The committee conduction the investigation, the investigation committee shall have the authority to review relevant documents and interview individual. The investigating committee may require a physical, mental and/or behavioral examination of the individual by health care professional(s) acceptable to it. The investigating committee shall make a reasonable effort to complete the investigation and issue its report within 30 days of the commencement of the investigation ...Well-Being Committee ...shall receive reports related to the health, well-being,

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| A 046 | Continued From page 58<br>or impairment of credentialed practitioners and ...in the event information received by the committee clearly demonstrates that the health or known impairment of a Medical Staff member poses an unreasonable risk of harm to [Facility] patients, that information may be referred to the MEC for formal action. Rules for Recusal (disqualification) ...When determining whether recusal in a particular situation is require, the Chief of Staff or committee chair shall consider whether the Interested Member's presence would inhibit full and fair discussion of the issue." | A 046 | | |
| A 047 | MEDICAL STAFF - BYLAWS<br>CFR(s): 482.12(a)(3)<br><br>[The governing body must] assure that the medical staff has bylaws.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review the Governing Body failed to ensure:<br><br>1. Medical staff followed the facility policy and procedures titled "Medication: Narcotics" and "Dangerous Drugs: Theft/Loss", when three of three Anesthesia Residents (physicians who finished medical school and are in training) (Resident 5, Resident 6, and Resident 7) accessed and prepared medications which were administered by Chair, Department of Anesthesia (MD 1) and documented as given by the resident. This failure resulted in MD 1's drug diversion.<br><br>2. Chief of Staff (MD 2) and Graduate Medical Education Program Director, Anesthesia (MD 4) reported MD 1's drug diversion to the Peer Review Committee (PRC) and Medical Executive Committee (MEC). This failure resulted in unused | A 047 | | |

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controlled medications (narcotics) and dangerous drugs to be unaccounted for and possibly diverted for MD 1's personal use.

Findings:

1. During an interview on 3/26/21, at 4:05 PM with Certified Registered Nurse Anesthetist (CRNA-Advance Practice Provider with specialized training in providing sedation medications) 1, CRNA 1 stated, she relayed her and other CRNA's concerns of MD 1's behavior, over use of controlled substances and diversion (unlawful channeling of regulated medication from legal sources for self use or to the illicit marketplace) in the summer of 2020 and again on January 2021 to Chief of Staff (MD 2) and/or Graduate Medical Education Program Director, Anesthesia (MD 4). CRNA 1 stated, after the complaints in the summer of 2020, MD 1 continued to work, but mainly with residents (physicians in training) and rarely with CRNAs. CRNA stated, the provider who removes the controlled substance from the Pyxis (an automated drug dispenser) was responsible for it. CRNA 1 stated, the provider can't hand over the controlled substances to another provider. CRNA 1 stated, the provider administers the medications to the patient, the waste (unused portion) must be discarded and documented.

During an interview on 3/24/21, at 5:25 PM, with Chief, Department of Anesthesia (MD 3), MD 3 stated, the practice of the anesthesia department has been, during the first three years of residency training, the residents pulled [removed medications from the Pyxis] medications for the supervising physician and prepared the medications for the surgical case. The resident

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handed the prepared medications to the supervising physician to administer. The supervising physician was "in charge of the meds ...meds pushed" and "deciding what needs to be given" to the patient.

During an interview on 3/29/21, at 4:05 PM, with MD 4, MD 4 stated, the attending (supervising) physician "chooses" the medications for the surgery. The resident will "obtain them from the Pyxis, draw them up into a syringe, label them, and give them to the attending physician. The attending will administer the intravenous (in the vein) medications."

During an interview on 3/29/21, at 5 PM, with MD 4, MD 4 stated, residents are employees of the hospital and must abide by all hospital policies and procedures.

During an interview on 3/25/21, at 2:08 PM, with Anesthesia Resident PGY 3 (Resident 5), Resident 5 stated, she "never pushed [give intravenous, in a vein] meds [medications] on induction [putting patients asleep for surgery] ...pushing meds is by supervising MD [physician] ...Resident records the meds given." The supervising physician would direct her what to document.

During an interview on 3/26/21, 11:51 AM, with Anesthesia Resident PGY 4 (Resident 7), Resident 7 stated, for every year in the anesthesia residency program, intravenous medications are given by the attending physician. Residents check them (medications) out from the Pyxis, "draw [put medication in a syringe] them up, label, dilute, date and give them to [physician]." No reconciliation was completed.

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The resident would record what the supervising physician directed.

During a concurrent interview, and record review, on 3/26/21, at 12:15 PM, with Resident 7, Resident 7 stated, the pharmacy will email the resident or provider if there are any controlled substance "discrepancies." "I [Resident 7] get an email, I correct the error, but I'm not necessarily the one who made the mistake ...the attending pushed meds [medications given via a vein] during care ... I didn't make mistake". "No matter who pulled [removed medications from Pyxis], the standard for CA 1-3 [anesthesia resident training years] supervising physician pushes meds" and resident records what the attending tells the resident to chart.

During a concurrent interview and record review, on 3/25/21, 6:58 PM, with Anesthesia Resident PGY 4 (Resident 6), Resident 6 stated, medications, including controlled substances, are left in the operating room unattended. Resident 6 stated, the supervising physician will give the medications the resident checked out from the Pyxis machine. She stated, "whoever checked out [medications] from the Pyxis is responsible [for custody of the medication]." Resident 6 stated, she has not had education regarding medication reconciliation of chain of custody of controlled substance.

During a review of the physician contract agreement titled, "[Faculty] Exclusive Professional Services Agreement: Regarding the Services of Anesthesiology", dated 10/1/20, the physician contract agreement indicated, " All services shall be provided in accordance with all applicable laws regulations, accreditation

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| A 047 | Continued From page 62<br>requirements, and Medical Staff Bylaws and Standards. Professional Standards Medical Group and its Providers shall perform their duties under this agreement in accordance with the rules of ethics of the medical profession and, in the case of CRNAs, the nursing profession ...in accordance with the appropriate standard of care for their respective professions and specialties, including the guidelines of the American Society of Anesthesiologist and the Medical Staff Bylaws ...Compliance with laws. Medical Group shall perform all services under this Agreement in accordance with any and all requirements and accreditation standards applicable to the [Facility] and service, including without limitation, those requirements imposed by the California Departments of Health Care Services and Public Health, The Joint Commission, and Medicare/Medicaid conditions of participation ....Medical Group shall at all times comply with bylaws, rules and regulations, policies and directives of the [Facility] and the Medical Staff ...Compliance Program. Medical Group will comply with all [Facility] policies, procedures, and code of conduct. Medical Group shall comply with regulations and standards as outlined by the Joint Commission and California Code to Regulations (CCR) Title 22, the State Board of Pharmacy, CMS Conditions of Participation, and other agencies having authority over the [Facility] and Department, to include medication safety and control, waste streams and HIPPA regulations, or as otherwise set forth in the Agreement ...Documentation requirements. Medical Group [shall promptly complete all records, forms and reports reasonably required by [Facility] and the Medical Staff ....Providers shall be accurate, complete and timely ...Medication Management. All Provides shall document and practice ... [And] | A 047 | | |

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shall achieve one hundred percent (100%) accountability for all drugs used and their disposition ...ensure proper disposal of sharps and/or pharmaceutical waste ..."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, "Abuse and losses of controlled substance will be reported in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical service, to the Chief Executive Officer and others per medical staff policy ..."

During a review of the hospital's pharmacy presentation titled, "Medication Management: Security, Waste & Disposal" by the Assistant Pharmacy Director, (ADPS) received 3/24/21, the presentation indicated, "Medication security. . . medications are never left unattended on counters or bedside a patient. . .IV [intravenous, given via vein] fluids and flushes are medications and must be secured like all others. . .prior to placing any controlled substance waste in the pharmaceutical waste bin, it must be rendered useless. Medications with diversion potential, such as Propofol should be rendered useless. . .Once medication orders are discontinued, promptly dispose of any medication remaining".

During a review of the hospital's policy and procedure (P&P) titled, "Pyxis Anesthesia System (PAS)", (RX 7.50.0), dated 2/9/21, the P&P indicated "To provide secure and identifiable access to medications ...the PAS is designed to help prevent inappropriate usage [of medications] in accordance with regulatory requirements by: strictly managing access ...providing adequate

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security for medications, including controlled substances (CS) ... Access to PAS will be limited to authorized, trained personnel ...Waste transactions must be created in PAS any time a controlled substance is removed from PAS but not completely administered. This activity must be performed no later than the end of the case ...The Chief of Anesthesiology (or designee) and Director Pharmacy (or designee) will be informed of any inconsistencies so that appropriate action(s) can be taken ...Anesthesia Providers are responsible for ensuring that physical counts agree with the system's internal count ...CS discrepancies must be resolved as soon as possible, the timeframe for discrepancy resolution should be no later than 24 hours from the time of discovery ...The individual responsible for creating a discrepancy [removed medication for PAS] is ultimately responsible for its' resolution ...If the discrepancy cannot be reconciled, the Chief of Anesthesiology is to immediately complete an occurrence report and immediately notify the Director of Pharmacy ....If the discrepancy cannot be satisfactorily reconciled, the Director of Pharmacy and Chief of Anesthesia will initiate appropriate action. Refer to AP 110 titled "Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse".

During a review of the hospital's policy and procedure (P&P) titled, "Medication: Narcotics", (PC 67), dated 8/23/16, the P&P indicated, "All controlled medications will be accounted for with appropriate documentation. Timely discrepancy resolution is necessary to comply with Federal and State theft/loss reporting requirements ...discrepancies are to resolved no later than 24 hours after discovery ...If a discrepancy cannot be

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| A 047 | Continued From page 65<br>satisfactorily resolved within 72 hours, the CNO [Chief Nursing Officer], VP [Vice President] of Human Resources, Risk Management and the DOP [Director of Pharmacy] will initiated appropriate action. (See Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse (AP 110)".<br><br>During a review of the hospital policy and procedures (P&P) titled, "Dangerous Drugs: Theft/Loss", (KDEP 11), dated 6/19/19, the P&P indicated, "The proper procedure in the case of theft/loss of controlled substance, chemicals listed in the Department of Justice Manual ("List 1 Chemicals, substances regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other dangerous drugs ...Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft ...loss in transit ...Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and /or | A 047 | | |

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other law enforcement agency. 6. California Department of Public Health."

2. During an interview on 4/1/21, at 12:20 PM, with the Governing Board (GB), the Chief Executive Officer (CEO) stated, "Diversion is a reality of the hospital and our [GB] responsibility is to create a culture to prevent it. The CEO stated, the GB is "responsible for medical and quality care and safety."

During an interview on 3/25/21, at 8:40 AM, with CRNA 1, CRNA 1 stated, she had relayed her and other CRNA's concerns of MD 1's behavior, over use of controlled substances, and diversion the summer of 2020 and again in January 2021 to MD 2 and MD 4. CRNA 1 stated, some concerns were: MD 1 would start cases and push anesthesia medications for other providers. When CRNA 1 returned to the patient there were no medications left. CRNA 1 stated, MD 1 started the anesthesia for me (CRNA 1). The patient "jumped" [move as if in pain] when the surgeon made the incision (cutting skin with a surgical knife). This lead CRNA 1 to "believe the medication charted as being given wasn't actually administered." CRNA 1 stated, she did not hear the outcome of her complaints.

During an interview on 4/1/21, at 8:10 AM, with MD 2, MD 2 stated MD 1's overuse and diversion of controlled substance came to his "attention in July 2020" via a MIDAS (occurrence reporting system) report from CRNA 1, and complaints from CRNA 1 and MD 4, and again in January 2021 from CRNA 1 and MD 4. MD 2 stated, MD 1 took a "leave of absence", joined the Well-Being Committee (assists physicians with matters of impairment, and maintenance of

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health) so an "investigation" for diversion and/or report to the Medical Board were not required. MD 2 stated, the Governing Body "gives the Director of Medical Staff (DMS) the authority to manage medical staff, and she "runs the show", and "DMS handles all of it."

During an interview on 3/24/21, at 5:25 PM, with Chief, Department of Anesthesia (MD 3), MD 3 stated, "looking back realized suspicious behavior" of MD 1. MD 1 would take "extra shifts, start cases for breaks, push all meds [anesthesia medications] up front, [I] would return from break ...no meds were left, and high dose given [to patients]." MD 3 stated, "if concerns are not reported in MIDAS, the problem will "not be known" and there will be "no monitoring ...no trends", and if the DMS does not refer provider (physician and CRNAs) occurrence to Peer Review Committee (PRC) or Medical Executive Committee (MEC), PRC and MEC will not be aware of the behavior and/or patient safety issue."

During an interview on 3/25/21, at 4:05 PM, with MD 4, MD 4 stated, after MD 1 joined the Well-being committee, it (MD 1's drug diversion) all became "confidential" and any action regarding PRC review, MEC review and investigation stopped. MD 4 stated, if the DMS does not believe an adverse event occurred, the MIDAS report would not reach RCA (root cause analysis, process to determine the initial cause of a problem), stage, PRC or MEC and the report closed with no further action required.

During an interview on 3/31/21, at 4:20 PM, with Director of Pharmacy Services (DPS), DPS stated, on 1/20/21, MD 1 "confessed to diversion"

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of controlled substance and impairment from May 2020 to January 20, 2021, and "Fentanyl (narcotic pain medication) was his [MD 1's] drug of choice." DPS stated, MD 1 reported to giving the patient a partial dose of the medication and "kept approximately 2/3 of the dose documented and administered" for himself.

During an interview on 3/28/21, at 2:40 PM, with VP Coordinator Surgical Services (VPCSS) VPCSS stated, reports of medical staff suspected of actual diversion, goes to the Medical Executive Committee and Chief of Staff, (MD 2) for review. VPCSS stated, if the DMS did not forward the MIDAS report to the PRC and MEC, no further action would be taken.

During an interview on 3/30/21 at 9:30 AM with Risk Management Specialist (RMS 1), RMS 1 stated, for occurrences to come to the attention to Risk a MIDAS report is filed. MIDAS reports would be reviewed by the Risk Management and if a provider was involved, it would be forwarded to the medical staff office. The medical staff office would decide if the MIDAS report needed to be forwarded to PCR or MEC. RMS 1 stated, the medical staff office has the authority to close the report with no further action required.

During the Medical Executive Meeting on 4/1/21 at 10:06 AM, with Medical Director Quality/ Patient Safety (MD 11), MD 11 stated, MIDAS reports are reviewed by the DMS if it involves a provider behavior or Patient safety issue. The medical staff office would determine if the provider was referred to PRC and MEC.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws,"

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dated 12/21/20, the P&P indicated "whenever a serious question has been raised regarding: the clinical competence or clinical practice of any member of the Medical Staff, including care, treatment to management of a patient or patients; the safety or proper care being provided to patients; conduct by any staff member considered lower than the standard of [Facility]. The matter may be referred to the Chief of Staff, the chair of the department, the chair of the standing committee, or the CMO. If the board becomes aware of information that raises concern about any Medical Staff member shall be referred the Chief of Staff, the chair of the department, the chair of the standing committee, CMO, or the CEO to the for review and appropriate action. "The person whom the matter is referred shall conduct or arrange an inquiry which shall include the Chief of Staff to determine whether the question raised has sufficient credibility to warrant further review and, if so, shall forward it in writing to the MEC". "No action taken pursuant to this Article shall constitute an investigation". "The Chief of Staff shall update the CEO". "In the event that the MEC fails to initiate an investigation in response to concerns raised about a Medical Staff member's competence, performance, or professional conduct in accordance with this article and the Board determines that such decisions is contrary to the weight of the evidence, the Board may direct the MEC to initiate such an investigation" (pg. 50)

During a review of the hospital's policy and procedure (P&P) titled, "District Bylaws" for [Facility], dated 4/27/20, the P&P indicated, "The [Facility] mission and vision are to "support the safety and quality of care, treatment and service [and] committed to ethical and legal business

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practices, integrity, accountability and excellence. . .Quality oversight responsibilities, the Board must. . .Understand and accept responsibility for the actions of all physicians nurses and other individuals who perform their duties in the organization's facilities. . .Carefully review recommendations of the Medical Staff. . .Fully understand the Board's responsibilities ad relationships with the Medical Staff and maintain effective mechanisms for communication with them. . .Monitor programs and services to ensure they comply with policies and standards ...take corrective action when appropriate ...understand and communicate the roles and function of the Board, committees, Medical Staff and management. . .Enforce Board and hospital bylaws rules and regulations. . .The Chief Executive Officer (CEO) "shall act on behalf to the Governing Body in the overall management of the [Facility]"...THE CEO shall select, employ had have authority to discharge any employee of the [Facility] other than any individual with the title or equivalent function ...The CEO shall keep abreast and be informed of new developments in the medical and administration areas of the hospital administration. . ."

During a review of the hospital's policy and procedure (P&P) titled, "Personnel management: Public Protection & Reporting Requirements", (KDEP 15), dated 11/10/2014, the P&P indicated "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or her license will be addressed promptly". The policy "outlined procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally,

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| A 047 | Continued From page 71<br>or physically impaired to the extent it effects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs ... in the interest of protecting the public, follows established procedures: Human Resource Policy HR 200, 'Drugs and Alcohol"; Administrative Policy AP 110, "Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse", and Reporting to the California Board of Pharmacy within 14 days of receipt or development of the following information with regards to any licensed individual employed by or with the pharmacy": theft, diversion, or self-use of dangerous drugs, physical or mental impairment. "<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug Diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect of drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be | A 047 | | |

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| A 047 | Continued From page 72<br>considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion".<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Suspected Illegal Substances", (AP 139), dated 1/29/20 , the P&P indicated the [Facility] follows the federal government Controlled Substance Act of 1970 (CSA) and defined "illegal substance [as] illegal drugs are substances, which individuals, by law, is not allowed to possess, use or distribute". [Facility] is entrusted with the responsibility of providing quality care and a safe, healthy, and efficient working environment ...if [Facility] staff members accidentally find any unusual substance which they suspect might be illegal drugs, staff are to notify their manager, [Facility] security, and Risk Manager immediately ...staff will provide the substance to Security staff ...Security will notify [local] police ...Security will provide the substance to the [Police] upon arrival ...[Police] will take possession of the illegal substance ....[Police] may write a crime report ...Security will prepare a Security Department Incident Report and forward to risk management." | A 047 | | |
| A 050 | MEDICAL STAFF - SELECTION CRITERIA<br>CFR(s): 482.12(a)(6)<br><br>[The governing body must] ensure that criteria for selection are individual character, competence, training, experience, and judgement. | A 050 | | |

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| A 050 | Continued From page 73 | A 050 | | |

This STANDARD is not met as evidenced by:
Based on interview and record review, the Governing Body failed to ensure four of four emergency department physicians ([Medical Doctor] MD 5, MD 6, MD 7, and MD 14) met contractual agreements for reappointments and /or continued membership. This failure resulted in MD 5, MD 6, MD 7, and MD 14 providing emergency medical care without the appropriate certifications required for the job.

Findings:

During a concurrent interview and credential file review, on 3/31/21, at 11 AM, with Director of Medical Staff (DMS), three emergency department physicians (MD 5, MD 6, and MD 7) credential files were reviewed. The emergency department physicians did not meet contractual requirements as follows:

1. DMS was unable to provide documented evidence of the required Advance Trauma Life Support (ATLS - systematic, concise approach to the early care of the trauma patient) Certifications for MD 5, MD 6, and MD 7.

2. DMS was unable to provide documented evidence of the required Advanced Cardiac Life Support (ACLS- group of procedures and techniques that treat immediately life-threatening conditions) Certification for MD 7.

3. DMS was unable to provide documented evidence of the required board certification (indicates the medical doctor has passed specialized training in a specific area of medicine) for Emergency Medicine for MD 7.

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4. DMS was unable to provide documented evidence of MD 5's competence for moderate sedation.

5. DMS was unable to provide documented evidence of privileges (right to practice) for Propofol (medication used to produce a loss of consciousness) for deep sedation (sleep) or Propofol infusions (given through the vein) for MD 5, MD 6, MD 7, and MD 14.

DMS stated, "Emergency room physician core privileges do not include anesthesia (lack of feelings of awareness and dulling of pain) privileges for example, deep and general anesthesia."

6. DMS was unable to provide documented evidence MD 5, MD 6, MD 7, and MD 14 agreed in writing to supervise residents (physicians in training after medical school).

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, the attending physician, "will be responsible for the medical care and treatment of the patient while in [Facility] ... "

During a review of the hospital's policy and procedure (P&P) titled, "Performance Management and Competency Assessment Program" (HR 213), dated 12/19/19, the P&P indicated "Competency is the demonstrated ability to integrate the knowledge, skills, and attitude required in a designated role or setting ...All employees must successfully complete all required training by the due dates established

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| A 050 | Continued From page 75<br>...Documentation of completion is recorded in the HR system and written documentation may be maintained in Human Resources or department employee's file."<br><br>During a review of the physician contract agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department," dated 8/20/2020, the physician contract agreement indicated, "Physicians shall be Board certified in Emergency Medicine or eligible to and actively pursuing Board Certification in emergency medicine ... All physicians must have successfully completed the American College of Surgeons Advanced Trauma Life Support ('ATLS") course, and all non-Board Physicians shall maintain current ATLS status. . .Medical Group shall and shall require all Medical Group Personnel to: provide services under this Agreement in accordance with appropriate standards of clinical practice, all applicable federal and state laws and regulations, all applicable rules in regulations of the Medical Board of California, and the Standards of the American Board of Emergency Medicine ...Comply with all applicable medical staff bylaws, rules, regulations, policies and procedures of the [Facility], including code of conduct and conflict of interest policies and procedures ...Comply with all applicable standards."<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws", dated 12/21/20, the Bylaws defined supervising physician as a "member of Medical Staff with clinical privileges who has agreed in writing to supervise or collaborate with an Advanced Practice Provider and to accept full responsibility for the actions of the Advanced Practice Provider | A 050 | | |

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| A 050 | Continued From page 76<br>..." The Bylaws defined Special Privileges as "privileges that fall outside the core privileges for a given specialty that require additional education, training, and/or experience beyond that is required for core privileges in order to demonstrate competence." To be eligible to apply initial appointment or reappointment to the Medical staff physicians ... meet any current eligibility requirements that are applicable to the clinical privileges being sought. . .if applying for privileges in an area that is covered by an exclusive contract, meet the specific requirements set forth in that contract. . . applicants who are not board certified at the time of application must be actively participating in the examination process leading to board certification. . .initial applicants who are not board certified and existing Medical Staff members seeking recertification may request additional time to obtain certification or recertification for one additional time period not to exceed two years ..." | A 050 | | |
| A 053 | CONSULTATION WITH MEDICAL STAFF<br>CFR(s): 482.12(a)(10)<br><br>[The governing body must:]<br><br>§482.12(a)(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual | A 053 | | |

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responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a).

This STANDARD is not met as evidenced by:
Based on interview and record review, the Medical Staff failed to ensure the Medical Executive Committee (MEC is a team of physicians that monitor and review physician behavior, conduct and patient safety) had the authority to oversee the professional conduct of the Chair, Department of Anesthesia (MD 1) and patient safety of the medical staff in providing safe and quality medical care for 311 hospital patients, as allowed by the medical staff bylaws, contract agreement, and policies. This failure resulted in the medical staff office making decisions about the professional behavior of MD 1 without MEC input review, which potentially compromised the health and safety of the patients when impaired Providers are allowed to continue to render medical care.

Findings:

During the Case Review Committee (CRC) Meeting on 3/24/21, at 7:15 AM, the Chief Executive Officer (CEO) stated the contracted staff, "abide by Policy and Procedures, contracts and medical staff requirements" and the Governing Body has "responsibility" of all staff and contracted staff for behavior, medical services and safety. The CEO stated the medical staff office "refused" to make it a "disciplinary level issue" and did not refer MD 1 to the Medical Board. The Governing Body "did not request MEC to investigate." CEO stated, MD 1 was

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given a choice to take a drug test or go to Well-Being". CEO stated, MD 1 "self-reported to the Well-Being Committee (a committee which assists physicians with matters related to prevention of impairment and maintenance of health, with particular attention to substance abuse or addiction, mental illness, or behavior), and enrolled in inpatient rehabilitation, and took a voluntary leave of absence". The CEO stated MD 1 did not "need to do a drug test" or "be suspended." CEO stated, since there was an "intervention ...don't need to suspend [MD 1]." The CEO stated, once in "Well-Being things are taken care of." Although the CEO stated it was a violation of [Facility] polices to commit a crime, falsify records and steal, the CEO stated MD 1 did not "violate" any of the [Facility] policies.

During an interview on 3/24/21 at 7:15 AM, with Director of Medical Staff (DMS), DMS stated "medical staff makes the determination" when MD 1 "returns to practice, no matter what condition". DMS stated she was acting on "behalf of the MEC". DMS stated if medical staff office is not "satisfied" with a physician's progress, medical staff office will refer the provider to "MEC". DMS acknowledged the medical staff office closed MD 1's MIDAS (a system for healthcare workers to report 'near misses' and patient safety concerns) report, indicating no further action required. DMS stated once MD 1 was referred to "Well-Being Committee", MD 1's diversion, substance use disorder became "confidential" and Medical staff has no obligation to refer to the Medical Board or investigate. The report was not referred to MEC or Peer Review Committee (PRC). DMS stated she reports directly to the CEO.

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| A 053 | Continued From page 79<br>During an interview on 4/1/21, at 8:10 AM, with Chief of Staff (MD 2), MD 2 stated, DMS is "my [MD 2's] boss"..."Co-boss" of the medical staff office. MD 2 stated the Governing Body "gives [DMS] the authority as medical staff director to manage ... medical staff" and "runs the show", and DMS "handles all of it". MD 2 stated, his responsibility was to refer to Director of Medical Staff (DMS), the Governing Body "did need to know about" MD 1's substance use disorder or diversion. And if medical staff office is "not satisfied" with MD 1, DMS would refer MD 1's controlled substance, diversion, and staff behavior reports to MEC. MD 2 acknowledged he did not initiate controlled substance audits, investigation, or monitoring on MD 1 in July 2020 or January 2021. MD 2 stated, MD 1 "admitted" to controlled substance theft, diversion and impairment, but MD 1 took a "leave of absence" and went to the Well-Being Committee; therefore; an "investigation" for diversion and controlled substance theft, and report to the Medical Board was not required. MD 2 stated, there were "no adverse events", safety concern or patient harm, so a referral to PRC or MEC was not needed. MD 2 stated, he determined no problem identified, and "satisfied".<br><br>During an interview on 3/31/21, at 4:20 PM, with Director of Pharmacy Services (DPS), DPS stated, on 1/20/21, he was "summoned" to DMS' medical staff office. DMS and MD 1 were at the meeting when MD 1 "confessed to diversion" of controlled substance from May 2020 to January 2021 and impairment. DPS stated medical staff was aware of the diversion because he was summoned to DMS' office. DPS stated it would be medical staff's decision to refer MD 1 to PRC and MEC. | A 053 | | |

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During an interview on 3/29/21 at 4:05 PM, with Graduate Medical Education (GME) Program Director/Vice-Chair Anesthesia (MD 4), MD 4 stated, he and MD 2 had a meeting with MD 1 to discuss controlled substance diversion and misuse complaints. MD 4 stated "drug testing was suggested" to MD 1, but MD 1 refused to submit. MD 4 and MD 1 discussed the Well-Being Committee, and MD 1 self-referred to the Well-Being Committee. MD 4 stated it is "confidential" once a provider enters the Well-Being Committee. MD 2 did not refer MD 1 to PRC or MEC for concerns about MD 1 diverting controlled substances and impairment.

During the Medical Executive Committee meeting and concurrent document review on 4/1/2021 at 10:06 AM, with Medical Director Quality/Patient Safety (MD 11), Chief, Department of Anesthesia (MD 3), MD 4, Critical Care Physician (MD 8) who were in attendance, the MIDAS reports filed for event dates 7/22/20, 1/8/21 and 1/20/21 were reviewed. The following were the MIDAS reports reviewed:

1. On 7/22/20, event date 7/22/2020, MD 2 submitted a MIDAS report about concerns of possible substance abuse by MD 1, after receiving a complaint from a Certified Registered Nurse Anesthetist (CRNA is an advanced practice nurse who administers anesthesia). The report was marked as a "physician issue, behavior, near miss safety event". MD 2 "determined the physician does not meet the criterion that would require a screening exam" and "there wasn't an issue". Medical Staff Office marks the event "from a medical staff perspective", "may close". Medical Staff Office did not refer MD 1 to PRC

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Review or MEC. There was no Root Cause Analysis (RCA is the process of discovering the underlying causes of the problems in order to identify appropriate solutions). MD 1's privileges were not suspended pending an investigation.

2. On 1/11/2021, event date 1/8/2021, CRNA 1 submits a MIDAS report about concerns of MD 1 overusing and diverting controlled substances and patient safety concerns. The report was marked "not a safety event. No known adverse outcome". The Director of Risk Management (DRM) reviews the MIDAS reports and sends a referral to California Department of Public Health (CDPH) and the Medical Director Quality/Patient Safety (MD 11) for review.. Medical Staff Office marks the event "from a medical staff perspective, may close." Medical Staff Office did not refer MD 1 PRC or MEC. There was no RCA. MD 1's privileges were not suspended pending an investigation.

3. On 1/21/2021, event date 1/20/2021, DPS submits a MIDAS report regarding MD 1's admission to diversion starting in July 2020 to January 20, 2021 and impairment due to substance abuse. The report was marked "not a safety event." MIDAS report was reviewed by Director of Risk Management (DRM). A self-referral was sent to CDPH on 2/5/2021. Medical staff office reviewed and marked "from a medical staff perspective, may close". Medical Staff Office did not refer MD 1 to PRC or MEC, and did not notify the pharmacy or Governing Board (GB) of the concerns about MD 1 diverting controlled substances. There was no planned investigation or RCA. MD 1's privileges were not suspended pending an investigation.

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| A 053 | Continued From page 82<br>During an interview on 4/1/21, at 11 AM, with Critical Care Physician (MD 8), MD 8 stated, he was the most senior physician on the MEC. MD 8 stated the MEC responsibilities are to review and monitor patient safety concern and physician behavior, and determines disciplinary action. MD 8 stated the MEC discusses findings with the Governing Board. MD 8, stated, provider behavior and patient care concerns need to be in MIDAS for it to reach Peer Review or MEC review. MD 8 stated, substance use disorder and diversion, should have "high" priority for review by MEC and [Facility]. MD 8 stated when reconciliation and diversion are concerns, "quality data is collected on physician investigations and adverse actions, and drug shortages." MD 8 stated, MEC was notified of MD 1 at its first meeting regarding MD 1 "last night [3/31/21]". He was not aware of MD 1's MIDAS reports for event dates 7/22/20, 1/8/21 and 1/20/21 until 3/31/2021. MD 8 stated, the reports are first reviewed by MD 11 and medical staff office. MD 1 was not referred to PRC or MEC because medical staff office determined it did not reach a patient safety or behavior concern that would require disciplinary action. MD 8 stated, MD I should have "done a urine toxicology (urine drug screen) and reported MD 1 to the Medical Board". MD 8 stated, DMS has "no authority" over the medical staff and does not supervise physicians". MD 8 stated, DMS is a "secretary". DMS "coordinates meetings and arranges rooms and takes notes at meetings."<br><br>During an interview on 4/1/21, at 11:15 PM, with MD 11, MD 11 acknowledged he was aware of MD 1's MIDAS report for event date 1/8/21, but he did not forward it to MEC. MD 11 stated someone has "leaked" information regarding diversion, drug paraphernalia, controlled | A 053 | | |

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substance disuse and impairment. MD 11 stated MD 1 was not referred to MEC or Peer review, and "not a risk to patient safety" because he went on a leave of absence. MD 11 stated there is "up to a three year back log of cases to review" for MIDAS occurrences.

During an interview on 4/1/21, at 11:30 PM, with MD 3, MD 3 stated DMS does not supervise physicians and is not a member of MEC. MD 3 states, DMS is a secretary, does paperwork, and runs the medical staff office. MD 3 stated, if physician concerns and patient safety issues are not reported in MIDAS, the problem will "not be known" to MEC or PRC, and there will be "no monitoring ...no trends". MD 3 stated the medical staff office needs to refer the provider's MIDAS report to PRC or MEC for possible actions.

During an interview on 3/30/21, at 9:30 AM, with Risk Management Specialist (RMS 1), RMS 1 provided MD 1's MIDAS report dated 1/11/2021 for event 1/8/2021. RMS 1 stated if there are "any problems" with medications, patient safety or behavior concerns, they are communicated via a MIDAS report. RMS 1 stated, the reports are reviewed by Risk and if a provider is involved the report is forwarded to medical staff office. RMS 1 stated, MD 1 and medical staff office are "responsible" for the review of MIDAS reports and refer adverse events, behavior affecting patient safety, or patient safety concerns to Peer Review Committee (PRC) or MEC. If the report is referred to PRC, the committee reviews and determines if disciplinary action is required. Once PRC determines disciplinary action is required, the MIDAS report involving the provider will be referred to the MEC. RMS 1 stated, if no adverse event of occurrence report referred to PEER,

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MEC, and the MIDAS report "would not reach RCA level", and "won't appear on adverse drug committee or risk management committee." RMS stated, MD 1 was not reported to PRC or MEC and MIDAS report, and thus would not reach RCA.

During a review of the hospital's P&P titled, "District Bylaws" for [Facility], dated 4/27/20, the P&P indicated the [Facility] mission and vision are to "support the safety and quality of care, treatment and service[and] committed to ethical and legal business practices, integrity, accountability and excellence ...Quality oversight responsibilities, the Board must ...Understand and accept responsibility for the actions of all physicians, nurses, and other individuals who perform their duties in the organization's facilities ...Carefully review recommendations of the Medical Staff ...Fully understand the Board's responsibilities ad relationships with the Medical Staff and maintain effective mechanisms for communication with them ...Monitor programs and services to ensure they comply with policies and standards ...take corrective action when appropriate ...understand and communicate the roles and function of the Board, committees, Medical Staff and management ... Enforce Board and hospital bylaws rules and regulations ...The Chief Executive Officer (CEO) "shall act on behalf to the Governing Body in the overall management of the [Facility] ..."

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Guidelines for 805.01 "CA Business Professional Code", (MS 33), dates 6/26/18, the (P&P) indicated before reporting actions under 805 and to the applicable licensing board, certain final decisions or

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recommendations of the Medical Executive Committee covered by this policy must satisfy four elements 1. Deny, terminate of restrict the clinical privileges of a practitioner; 2. Recommendation by the Medical Executive Committee; 3. Following a formal investigation and 4. MECs that any of the following acts have occurred. For example, incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or herself, any controlled substance; repeated acts of clearly excessive prescribing; or sexual misconduct with one or more patients."

During a review of the hospital's P&P titled, "Medical Staff Well-Being Committee" (MS 02), dated 6/26/17, the P&P indicated, the" responsibility of the Well-Being Committee is advisory in nature and not a substitute for personal physician of a disciplinary body... It will report to the MEC and to the physician in question... Well-Being Committee should serve only as an advisory and monitoring body, conducting inquiries and evaluations, and making reports to the governing committee as necessary."

During a review of the hospital's P&P titled, "Peer Review Process" (MS 8710.PR), dated 2/9/21, the P&P indicated, the Medical Staff assess each credentialed practitioner's professional performance and behavior as part of its ongoing quality and patient safety, credentialing, privileging and corrective action responsibility, including clinical judgement, and appropriate documentation. Cases recommended for medical staff peer review may be generated from, the list

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| A 053 | Continued From page 86<br>is not all inclusive, Occurrence Reports, Patient Safety Committees, Quality/Safety Departments, Risk Management Department, Midas Reporting process and so forth. Cases recommended for Peer Review are preliminarily screened by Peer Review (PR) Coordinator and presented to the Medical Director or Chief Medical Officer. . .If initial reviewer indicates potential conflict of interest, Peer Review (PR) Coordinator will assign case to next reviewer. The Chief of Staff will make the final decision on referral to peer review. The PRC will meet monthly, evaluate cases, and make a preliminary determination which will be forwarded to the staff member for reply within 30 days. The PRC assigns a final case determination. Results of the peer review process may range from identified opportunities for enhancing care/documentation to identified opportunities of critical importance for improving care. System level opportunities or individual Practitioner issues may be identified".<br><br>During a review of the hospital's P&P titled, "Impaired Provider Policy" (MS 40), dated 5/31/2018, the P&P indicated, "substance abuse can adversely impact patient care and workplace safety. Use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and advance practice providers (APP, include CRNAs, NPs, PAs, ) to provide services and may endanger the individual, his or her co-workers, patients and public ...Whenever a hospital staff members observes evidence of possible impairment by a member pf the medical staff or APP, while on hospital premises, the staff member shall immediately inform his or her supervisor who shall inform the CEO or representative ... he Chief of Staff or designee shall promptly conduct | A 053 | | |

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or supervise the administration of a Screening Physical Exam of the practitioner ...[and] ask the suspect practitioner to agree to a drug test or alcohol or other testing ..., "Any violation of this policy shall require testing."

During a review of the hospital's P&P titled, "Code of Conduct for Medical Staff & Advanced Practice Providers" (MS 47), dated 1/30/2019, the P&P indicated, "Practitioners have a responsibility for the welfare of their patients...The safeguarding of patient care and safety is paramount, and the Medical Staff will enforce this policy with disciplinary measures whenever necessary." Examples of "inappropriate behavior means conduct that is unwarranted and reasonable interpreted to be demeaning or offensive," or "blatant failure to respond to patient care needs or staff requests."

During a review of the hospital's P&P titled, "Medical Staff Bylaws", the P&P indicated, "the Chief of Staff shall update the CEO, in the event that the MEC fails to initiate an investigation in response to concerns raised about a Medical Staff member's competence, performance, or professional conduct in accordance with this article and the Board determines that such decisions is contrary to the weight of the evidence, the Board may direct the MEC to initiate such an investigation ...The committee conducts the investigation, the investigation committee" shall have the authority to review relevant documents and interview individual." The investigating committee "may require a physical, mental and/or behavioral examination of the individual by health care professional(s) acceptable to it." The investigating committee shall make a reasonable effort to complete the

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investigation and issue its report within 30 days of the commencement of the investigation ...The MEC may accept, modify, or reject any recommendations it receives from an investigating committee

During a review of the hospital's P&P titled, "Medical Staff Rules and Regulations", adopted 12/21/2020, date approved 12/21/2020, indicated. The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in [Facility] ...prompt and accurate completion of portions to the medical record for which he or she is responsible ... performing all other duties described in these Rules and Regulations ...Abuse and losses of controlled substance will be reported in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical service, to the Chief Executive Officer and others per medical staff policy ... Medication orders will be entered directly into the electronic medical record by the ordering physician ... accurate and complete medication reconciliation ... All verbal orders will include the date, and time of entry into the medical record, identify the names of the individual who gave, received and implemented the order, and then be authenticated with the date and time by the ordering practitioner".

During a review of the hospital's policy and procedure (P&P) titled, "Personnel management: Public Protection & Reporting Requirements", (KDEP 15), date created 7/10/2014, date approved 11/10/2014, indicated "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or

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| A 053 | Continued From page 89<br>her license will be addressed promptly". The policy "outlined procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it effects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs ... in the interest of protecting the public, follows established procedures: Human Resource Policy HR 200, 'Drugs and Alcohol'; Administrative Policy AP 110, 'Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse', and Reporting to the California Board of Pharmacy within 14 days of receipt or development of the following information with regards to any licensed individual employed by or with the pharmacy: theft, diversion, or self-use of dangerous drugs, physical or mental impairment." | A 053 | | |
| A 083 | CONTRACTED SERVICES<br>CFR(s): 482.12(e)<br><br>The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the Governing Body failed to: | A 083 | | |

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1. Ensure the medical staff followed its policy and procedures in handling unusual occurrences of deaths in the Emergency Department (ED) for two of two sampled patients (Patient 1 and Patient 2). These failures resulted in the unclear causes of death for Patient 1 and Patient 2.

2. Take measures to secure medical equipment, such as syringes and needles from being accessed by one of one contracted and unauthorized staff (Scribe [SC 1]). This failure increased the possibility of diversion (the unlawful channeling of regulated medication from legal sources for any illicit use) and use of illegal substances.

3. Provide a process to prevent and intervene when the use of drug paraphernalia (syringes, needles, alcohol swabs) and illegal substances were discovered in the emergency department. This failure place staff, visitors, and the public at risk for injury.

Findings:

1a. During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive [gets worse over time] lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure is a condition in which the heart's function as a pump is not enough to supply adequate amount of blood to the body),...brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60

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(Oxygen level in the blood. A reading of 60 mmHg [millimeters of Mercury is a unit of measurement] or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95% [percent]) on room air, and only improved to 70 with 15 L (liters, unit of measurement) NRB (non-rebreather mask- a device used to assist in the delivery of higher concentration of oxygen)...Vital signs were: HR (heart rate) 128 bpm (beats per minute, normal HR is 60 to 100), RR (respiratory rate) 40 (normal RR is 12 to 18), BP (blood pressure) 138/114 (normal BP is 120/80). High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress...the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing), high flow nasal cannula, and eventually taking off the NRB mask. Patient was then later intubated (a tube is inserted down the throat and into the windpipe to make it easier to get air into and out of your lungs) for respiratory failure and inability to tolerate BIPAP."

During a review of Patient 1's "Critical Care Progress Notes," dated 12/21/20, at 11 PM, the Critical Care Progress Notes indicated, "In the emergency department, [Patient 1] was found to be hypotensive (low blood pressure), tachypneic, (rapid respiratory rate), and tachycardic (rapid heart rate). The patient coded (medical emergency in which one is found to be unresponsive, pulseless, and not breathing) and after 10 minutes and five rounds of CPR (cardiopulmonary resuscitation - an emergency lifesaving procedure performed when the heart stops beating), achieved return of spontaneous

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circulation (ROSC). Patient 1 was placed on Propofol (anesthetic) drip, 2000 mg in 100 ml (milliliter, a unit of measurement) at 5mcg/kg/min (micrograms per kilogram per minute - units of measurements) for post-intubation sedation."

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 11:19 PM, the Reexamination/Reevaluation Notes and Resident Attestation documented by Emergency Department Physician (MD 5) indicated, "...ED RN (Registered Nurse) reported wide complex rhythm on the monitor and she noted no pulses. Compressions started immediately and had an ROSC (return of spontaneous circulation) after approximately 10 minutes of downtime." On 12/22/20, at 1:54 AM, MD 7 documented MD 5 discussed the patient's care with [Patient 1's] sister extensively, and per his sister's wishes, placed [Patient 1] on Comfort Care Status (a form of medical care that focuses on relieving symptoms and optimizing comfort). MD 7 administered Fentanyl (narcotic pain medication) 100 mcg. IV (intravenous-into the vein), withdrew the endotracheal tube (a flexible plastic tube that is placed through the mouth into the windpipe to open the airway and help a patient breathe), and mechanical ventilation (a machine that helps a patient breathe), and vasopressor (any medication that tends to raise low blood pressure) support. MD 7 pronounced Patient 1 dead at 1:53 AM.

During an interview on 3/23/21, at 3:46 PM, with MD 5, MD 5 stated he does not "do coroner referrals" for unusual deaths or circumstances, even if Scribe (SC 1), who also happens to be Patient 2, accessed and "violated" Patient 1's IV line (medications and fluids given into a vein) and

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removed medications.

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, the document indicated,"Resident 1 (ED Resident Post Graduate Year 1 [PGY] - a physician in training) evaluated [Patient 1] at 11:00 PM. Patient 1 was on a heart monitor and had an arterial line (access to an artery for blood pressure readings and blood for laboratory) with a blood pressure of 122/91. [Patient 1's] vital signs-- temperature 36.6 centigrade (normal average body temperature 36.1), heart rate 104, respiratory (breathing) rate 22, blood pressure 124/81, SP02 90% (oxygen content of blood, normal 95 to 100%)." The resident documented, Patient 1 had a successful resuscitation (life-saving efforts with CPR, cardiopulmonary resuscitation) efforts and ROSC (return of spontaneous circulation), was on a ventilator (machine that breathes for a patient), and waiting to be moved to the intensive care unit (ICU, a place where very sick patients go).

During a concurrent interview and review of Patient 1's ED medical record, on 3/23/21, at 4 PM, with MD 5, Patient 1's ED medical record was reviewed. Patient 1's ED record indicated, at 12:35 AM Patient 1's vital signs were: blood pressure of 122/91, heart rate 104, respiratory rate 22 and ventilator in use. There was no documentation of a patient assessment, oxygen use, heart monitor readings or ventilator settings (rate of breathing an oxygen given to patient) of Patient 1 by MD 5, Resident 1 or ED nursing. At 12:41 AM, the medical record indicated Patient 1 was on "Central Telemetry and cardiac monitoring (heart monitor located at the nurse's station, used to continuously monitor a patient's heart rate and rhythm)". The medical record indicated a

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recording of Patient 1's heart: "Atrial Flutter [irregular rhythm], a heart rate of 70 beats per minute, and a BBB (bundle branch block, an abnormal heart beat path in the heart). There was no documentation of a patient assessment, oxygen use, heart monitor readings, or ventilator settings of Patient 1 by MD 5, Resident 1 or ED nursing. MD 5 verified the findings.

Between 12:41 AM and 1:41 AM, Patient 1, who was still a full code (means that if a person's heart stops beating and/or they stop breathing, all resuscitation procedures will be provided to keep them alive), was intubated, and waiting to be admitted to the ICU. Patient 1's status was changed to "comfort care" and withdrawal of medical care. There was no documentation of vital signs, temperature, cardiac monitoring, oxygen delivery, ventilator use, ECG (heart test to determine rate, rhythm and function), reflexes (show brain is connected to body motor function), apnea test (determine if patient can breathe on own without a machine), examine the heart, lungs and nervous systems, or normal laboratory values. There were no documented orders for a POLST (stands for Physician's Orders for Life-Sustaining Treatment- life directives stating wishes for full resuscitation, limited resuscitation or natural death. This must be signed by the patient and/or patient representative, and a physician. It requires neurology [physician who evaluates the nervous system] consult or palliative care [determine medical care wishes for diseases when a patient has less than 2 years to live to end of life]) consult for Patient 1. MD 5 verified the findings.

During an interview on 03/23/2021 at 3:46 PM, with MD 5, MD 5 stated he "recalls" Patient 1

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wishes to be a "full code", but "can't recall" how the "full code" was changed to "comfort care". MD 5 stated, Resident 1 was "taking care of [Patient 1]".

During an interview and concurrent record review, on 3/23/21 at 8:35 PM, with ED Resident PGY 1 (Resident 1) Patient 1's ED medical record was reviewed. Resident 1 was unable to find documented orders for a POLST (Physician Orders for Life Sustaining Treatment) form, a neurology consult (Neurologists are doctors who diagnose and treat problems with the brain and nervous system). or a palliative care (Palliative care is specialized medical care for people living with a serious illness) consult. Resident 1 stated, "Nothing more accurate than what is in the chart." Resident 1 acknowledged Patient 1 was a full code, intubated, and waiting to be admitted to the ICU. Resident 1 stated, he "decided" poor out come" and 'comfort care'" for Patient 1. Resident 1 stated he did not speak with the family or patient representative regarding changing Patient 1's full code status to "comfort care". Resident 1 stated he "believes" MD 5, his supervising physician, spoke with family about "comfort care" and "patient status". Resident 1 stated he did not speak with MD 5 regarding Patient 1's code status, nor did he document any communication with MD 5. Resident 1 acknowledged he did not complete an assessment to determine Patient 1's viability or signs of life, or reasons to withdraw medical care.

During a concurrent interview and record review, on 3/29/21, at 6:17 PM, with Critical Care Physician (MD 18), Patient 1's "ED medical record," dated 3/22/21, the record indicated, "[Resident 4] wrote a death summary for [Patient

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1] at 6:37 AM and was co-signed by [MD 18]. [Resident 4] did not provide a cause of death for [Patient 1]. [Resident 4] documented "comfort care while in the ED. Patient passed peacefully with [ED] staff at bedside". MD 18 stated he spoke with Resident 4 and was "surprised the resident made Patient 1 'comfort care' after a successful ROSC (return of spontaneous circulation), pending ICU admission, and medical care withdrawn. MD 18 stated he was not informed as to why Patient 1's status "changed" from a full code. MD 18 stated, he "did not have answers" and there was no documentation. MD 18 stated, he did not sign-off Patient 1 was not a corner's case. MD 18 stated the ICU team consulted on Patient 1 and was never transferred to the ICU. MD 18 stated the ICU team was not involved with or present at Patient 1's death.

During a review of Patient 1's ED medical record, dated 3/22/21, the medical record indicated, MD 7, who had been caring for Patient 1 for a few minutes, pronounced Patient 1 dead at 1:53 AM.

During a concurrent interview and review of Patient 1's ED medical record, on 3/29/21, at 7:05 PM, with the Emergency Department Physician (MD 7), Patient 1's ED medical record, dated 3/22/21, indicated, MD 7 was unable to find documentation of vital signs, temperature, cardiac monitoring, oxygen delivery, ventilator use, ECG, reflexes, apnea test, heart exam, lungs and nervous systems, or normal laboratory values. MD 7 acknowledged he did not determine Patient 1's viability, or signs of life, or reasons to withdraw medical care. MD 7 acknowledged there were no interventions taken to persevere Patient 1's life. MD 7 stated he pronounced Patient 1's death after the nurses informed him Patient 1 did

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not have a pulse or blood pressure. The medical record did not indicate any documentation of Patient 1's status or vital signs after 12:41 AM on 3/22/20.

During a review of the video footage on 3/30/21, at 3:30 PM, the video footage dated 12/21/20 taken at 2:12:22 AM indicated, a social worker and a sheriff entered Room 19, the room of Patient 1, who was deceased.

During a concurrent interview and video viewing, on 3/30/21, at 3:35 PM, with Security Services Manager (SSM) and Security Officer (SO 1), SO 1 identified the individuals in the video. SSM stated after the death of Patient 1, the sheriff's office takes a report, speaks with the physician, and determines if an autopsy is needed. SO 1, who was on scene during the events of SC 1/Patient 2's resuscitation and death, wrote a report. SO 1's report indicated, Registered Nurse (RN 3) "informed security during our debriefing that she believed [Scribe SC 1/Patient 2] gained access to the drug by filling two syringes with Propofol (anesthetic) container that was meant to be given to a patient in room 19 of the ED". SO 1 stated he did not receive any syringes from ED staff found with SC 1/Patient 2.

During an interview on 3/26/21, at 2:45 PM, with Detective, Tulare County (DET), DET stated the [Facility] "signed-off as a non-coroner case because [Patient 1] died of a cardiac arrest". DET stated, he interviewed ED staff-- RN 1, RN 2, RN 3, and RN 16, and the Security Officer Supervisor (SOS 2) about the death of SC 1/(Patient 2). DET stated the ED staff reported, "A couple of syringes were found with [SC 1/Patient 2]" and was informed it was "Propofol" and the medication

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"was short on another patient". DET stated his documents indicated, MD 18 "signed off" as a "non-coroner case".

During a review of the Physician Contract Agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department", dated 8/20/20, the Contract indicated, "Medical Group shall at all times comply with bylaws, rules and regulations, policies and directives of the [Facility] and the Medical Staff ...Compliance Program. Medical Group will comply with all [Facility] policies, procedures, and code of conduct. The agreement indicated, the "Medical Group and its personnel shall document exclusively in the electronic medical record.... If Medical Group uses scribes, who are not clinical staff, Medical Group shall be entirely responsible for such scribes, and ensure that they follow all policy and procedures of the [Facility], and all relevant laws and regulations".

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws", dated 12/21/20, the P&P indicated, Providers are "to refrain from delegating responsibility for hospitalized patients to any individual who is not qualified or adequately supervised (Scribe, Resident); to refrain from deceiving patients as to the identity of any individual providing treatment or services".

During a review of the hospital P&P titled, "Medical Staff Rules and Regulations", dated 12/21/20, the P&P indicated Autopsy Coroner cases: "When an autopsy is performed a provisional anatomic diagnosis should be documented in the medical record within three

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says and the complete report should be made part of the medical record within 30 business days ..." "Per Health and Safety Code Sections 102800 and 102975 the medical certification of the cause of death within in the death certificate will be completed by the attending physician (or his designee) within 15 hours of the tie of death ...Autopsies should be considered for unusual death ...deaths in which an autopsy may help explain unknown or unanticipated medical complications ...In addition if not otherwise attainable from the patient's medical record, the Pathology Department will discuss the case with the attending physician (or his or her designee) prior to starting of the autopsy so that the clinical diagnosis and any concern including any infection hazards, can be provided to the pathology staff". The policy further indicated, "The attending physician shall be responsible for requesting a consultation ... the attending physician will make reasonable attempts to personally contact the consulting Practioner to discuss the consultation request". P&P indicated, "Progress notes: Clinically pertinent progress notes shall be recorded at the time of observation, and must be legible, dated, and timed, shall be documented with a frequency consistent with the acuity of medical problems to reflect patient's condition and plans for management, and shall always be written in a manner with such clarity and frequency that another Practitioner could quickly understand the [patient's status ....Any complications must also be documented ...."

1b. During a concurrent interview and review of the video footage of the incident, on 3/26/21, at 10:18 AM, with Security Services Manager (SSM), SSM stated, "On 12/22/20, at 12:34 AM,

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[SC 1] who is also [Patient 2], was observed entering [Patient 1's] room, in room 19. Near the door, (SC 1/Patient 2) was opening a drawer containing syringes and a drawer above it containing needles, and next (SC 1/Patient 2) discarded a small package into the trash."

During an interview on 3/29/21, at 8:15 PM, with Security Officer (SO 1), SO 1 stated, he was on scene when SC 1/Patient 2 entered the ED public bathroom and started a report after SC 1/Patient 2's death. SO 1's report indicated, Registered Nurse (RN 3 ) "informed security during our debriefing that she believed SC 1/Patient 2 gained access to the drug by filling two syringes with Propofol (sedation medication) container that was meant given to a patient in room 19 of the ED". SO 1 stated he did not receive any syringes from the ED staff found with SC 1/Patient 2.

During an interview on 3/30/31, at 3:30 PM, with SO 1, SO 1 identified the individuals in the video, which was later confirmed by the Emergency Department Nurse Manger (EDNM). EDNM also verified the small package SC 1/Patient 2 discarded into the trash was a wrapper of a gauge 18 needle.

During a concurrent interview and record review, on 3/24/21, at 2:35 PM, with the Emergency Department Physician (MD 6), Patient 1's History and Physical (H&P), dated 3/21/20, was reviewed. MD 6, stated he "considered ingestion" as the cause of overdose. SC 1/(Patient 2) had been receiving medical care at the [Facility] for several years. The history and physical did not indicate MD 6 documented in SC 1/(Patient 2's) electronic medical record information regarding past medical history, including major depression,

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chronic back pain, generalized anxiety disorder, or a complete medication list. The H&P did not include the syringes filled with Propofol, empty syringes and needles found with SC 1/(Patient 2) in the bathroom. MD 6 stated he could "not recall" why Propofol was not included in the H&P or as a reason for the overdose and death.

During an interview on 3/31/21, at 6:50 PM, with Emergency Department Technician (EDT), EDT stated the "whole room- (RN 1, RN 3 RN 2, RN 4, RN 16, MD 6, Respiratory Therapist [RT 1], and the Resident Physicians) --knew about the Propofol." EDT stated he witnessed, after SC 1/Patient 2's resuscitation in room 21, "someone from room 21 [can't recall who] bringing a 60 ml (milliliter, a unit of measure) syringe with a needle filled with what looked like Propofol. EDT stated MD 6 was notified. The House Supervisor (HS) was present and told the person to discard the 60 ml syringe with needle and "put in the sharp container."

During an interview on 3/23/21 at 8:30 PM, with RN 3, RN 3, RN 3 stated two syringes were found on SC 1/(Patient 2), one 20-30 ml syringe, which had enough remaining in the syringe "to know what it was. . .white milky substance. . .looked like Propofol, and the other filled with a needle attached." After the resuscitation efforts were over, RN 3 stated another, a 20 ml syringe with Propofol was found in room 21 on the ground. RN 3 stated MD 7 and MD 6 were present when she reported it to the police, security, and EDNM. RN 3 stated, the police instructed her to "throw it away".

During an interview on 3/23/21, at 6:15 PM and 3/23/21 at 8:50 PM, with RN 1, RN 1 stated MD 6

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"questioned the RNs of the events" surrounding SC 1/(Patient 2). RN 1 stated "MD 6 knew about SC 1/(Patient 2)," how he was found and the "white substances in the syringes, and blood in smeared on the wall in the bathroom, and during the code we found more syringes". RN 1 acknowledged she did not provide security, police or corner with Propofol syringes and/or needles found on SC 1/(Patient 2).

During an interview on 3/23/21 at 6:15 PM, with RN 2, RN 2 stated two 20 to 30 ml syringes; one empty with a needle attached and "could tell it had Propofol in it", and the other was "full of Propofol" were found in SC 1/Patient 2's arm. RN 2 acknowledged he did not provide security, police or corner with Propofol, syringes and/or needles found on SC 1/Patient 2).

During an interview on 3/29/21, at 7:05 PM, with MD 7, MD 7 stated SC 1/Patient 2 was found in the ED public bathroom, adjacent to Room 19 in Zone 2 (ED Unit for critical patients) and was moved to room 21 for resuscitation. MD 7 stated "needles" and "big syringes, 60 ml" of Propofol were found. MD 7 acknowledged he did not provide security, police or corner with Propofol, syringes and/or needles found on SC 1/Patient 2.

During interviews on 3/26/21 at 10:18 AM and 3/29/21 8:15 PM, with Security Officer (SO 2) SO 2 stated, on 12/22/20 after SC 1/Patient 2's death, RN 3 also informed security during our debriefing that she believed SC 1/(Patient 2) gained access to the drug by filling two syringes with Propofol container that was given to a patient in room 19, Zone 2. SC 1/Patient 2 went inside Zone 2's restroom where he ultimately "injected himself with the drug". SO 1 stated he did not

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receive any syringes that contained Propofol.

During an interview on 3/26/21, at 2:45 PM with the Detective, Tulare County (DET), DET stated on 3/22/20, at 4:06 AM, he interviewed the following ED staff: RN 1, RN 2, RN 3, RN 16, and Security Officer Supervisor Nights (SOS 2). DET stated ED staff reported, "a couple of syringes were found with (SC 1/Patient 2)" and was informed it was "Propofol" and the medication "was short on another patient". DET stated he did not receive any syringes that contained Propofol. DET stated the hospital "disposed" of the syringes and he was not able to pass on any syringes or medications to the pathologist for testing and toxicology screen (laboratory test to identify substances). DET stated Propofol screening was not ordered by the pathologist.

During a review of SC 1/Patient 2's Emergency Department Documentation, dated 3/22/20, the physician notes indicated, "On 3/22/20, at 4:14 AM, [MD 6] completed the physician's note on [Patient 1] and documented the cause of death was cardiac arrest (heart stopped beating)."

During an interview on 3/24/2021, at 2:35 PM, with MD 6, MD 6 stated, "syringes were found in his pockets ...and someone might have said Propofol ...can't recall", and could "not recall" why Propofol was not included as a reason for the overdose and death. MD 6 did not provide security, police or corner with Propofol, syringes and/or needles found on SC 1/Patient 2.

During an interview on 4/15/21 at 1:15 PM, with CORONER (COR), COR stated SC 1/Patient 2's medical record, DET report, or other information were not available to him before completing the

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autopsy on SC 1/Patient 2. COR stated he was not aware of SC 1/Patient's 2 past medical history of severe depression and multiple prescriptions, or circumstances of SC 1/Patient 2's death. COR confirmed he did not receive any syringes or needles containing Propofol or a milky white liquid. COR stated he ordered the standard toxicology screening, but since he was unaware of the Propofol found with SC 1/(Patient 2), he did not order the screening. COR stated, there was an error in the autopsy report, he did not see earlier. COR stated, SC 1/(Patient 2)'s venlafaxine (anti-depression medication) blood level was within normal range. SC 1/(Patient 2)'s records reflected prescriptions and use of venlafaxine for over 9 months. COR stated he will need to review the medial records and speak with DET about the possible cause of SC 1/(Patient 2)'s death.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations", dated 12/21/20, the P&P indicated, "Autopsy Coroner cases: "When an autopsy is performed a provisional anatomic diagnosis should be documented in the medical record within three days and the complete report should be made part of the medical record within 30 business days ..." "Per Health and Safety Code Sections 102800 and 102975 the medical certification of the cause of death within in the death certificate will be completed by the attending physician (or his designee) within 15 hours of the time of death ...Autopsies should be considered for unusual death ...deaths in which an autopsy may help explain unknown or unanticipated medical complications ...In addition if not otherwise attainable from the patient's medical record, the Pathology Department will

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| A 083 | Continued From page 105<br>discuss the case with the attending physician (or his or her designee) prior to starting the autopsy so that the clinical diagnosis and any concern, including any infection hazards, can be provided to the pathology staff... The attending physician shall be responsible for requesting a consultation ... the attending physician will make reasonable attempts to personally contact the consulting Practitioner to discuss the consultation request... Progress Notes: Clinically pertinent progress notes shall be recorded at the time of observation, and must be legible, dated, and timed, shall be documented with a frequency consistent with the acuity of medical problems to reflect patient's condition and plans for management, and shall always be written in a manner with such clarity and frequency that another Practitioner could quickly understand the [patient's status...Any complications must also be documented..."<br><br>During a review of the Physician Contract Agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department", dated 8/20/20, the physician contract agreement indicated, "Medical Group shall at all times comply with bylaws, rules and regulations, policies and directives of the [Facility] and the Medical Staff...Compliance Program. Medical Group will comply with all [Facility] policies, procedures, and code of conduct...neither Medical Group nor any Provider shall act in any manner that conflicts with or violates the Standards...Medical Group shall comply with regulations and standards as outlined by the Joint Commission and California Code to Regulations (CCR) Title 22, the State Board of Pharmacy, CMS Conditions of Participation, and other agencies having authority over the [Facility] | A 083 | | |

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and Department...complete accurate and timely medical records of service provided in the Department."

During a review of the hospital's policy and procedure (P&P)) titled, "Coroner's Cases", (PC 64), dated 5/16/2018, the P&P indicated, "The law requires certain cases to be reported to the coroner. A nurse, physician, or unit secretary may report the case...In no instance should a body under the jurisdiction of the Coroner be released to a funeral establishment or removed from surgery or the emergency room, except upon explicit instructions from the coroner's office. Examples of deaths that are reported to the coroner's office are suicide (known or suspected), homicide (known or suspected), involving any criminal action or suspicion of a criminal act, drug addiction, physician unable to state cause of death, and all deaths in which the patient is comatose throughout the period of physician attendance."

During a review the hospital's P&P titled, "Autopsy, Arranging for", (PC 38), dated 10/30/2020, the P&P indicated, "An autopsy- a postmortem examination to determine the cause of death. The house supervisor shall be responsible for making autopsy arrangements and sending "patient's entire chart; do not break down the chart".

During a review of the hospital's policy and procedure (P&P) titled, "Dangerous Drugs: Theft/Loss", (KDEP 11), dated 6/19/19, the P&P indicated, and outlined the proper procedure in the case of theft/loss of controlled substance, chemicals listed in the Department of Justice Manual (List 1)... "Chemicals, substances

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regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other dangerous drugs...Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft. . loss in transit...Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and /or other law enforcement agency. 6. California Department of Public Health."

2. During an interview on 3/26/2021, at 4:30 PM, with Certified Registered Nurse Anesthetist (CRNA 3), CRNA 3 stated needles are locked and treated like "non-controlled substances."

During an observation, interview, and record review, on 3/30/31 at 6:30 PM, with the Director of Emergency Services (DES) and RN 4 in the Emergency Department Zone 2, Room 19 was observed where Patient 1 was cared for on

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12/21/20 to 12/22/20 and the same room SC 1 entered, as seen on video surveillance, on 12/22/20 at 12:34 AM. Inside room 19, to the left of the entrance, was a mobile cabinet over six feet tall, and consisted of nine drawers, called a "C-locker" where intravenous fluids, intravenous and blood tubing, alcohol swabs, laboratory supplies, needles and syringes, and others were stored. In drawer five of the C-locker were the needles and in drawer eight of the C-locker were the syringes. The cabinet was unlocked and open. All supplies were easily accessible. DES stated, "it should be locked at all times except when in the room caring for a patient."

During an interview on 3/31/21 at 6:50 PM, with Emergency Department Technician (EDT), EDT stated the "C-lockers are always open...for "easy access" of supplies, including needles and syringes.

During an interview on 3/23/21, at 8:30 PM, with RN 3, RN 3 stated SC 1 "was everywhere in the Emergency Department", and it "would not be unusual for SC 1 to get supplies for the nurses." RN 3 stated two syringes were found on SC 1, one 20-30 ml (milliliter, a unit of measure) syringe had enough white substance remaining in the syringe. . .and the other filled with a needle attached."

During an interview on 3/23/21, at 6:15 PM, with RN 2, RN 2 stated syringes and needles are locked in cabinets, "but extra syringes can be left out", and "carts and drawers are not locked." RN 2 stated two 20 to 30 ml syringes; one empty with a needle attached and the other was "full of Propofol (sedation medication)" were found in the bathroom with SC 1.

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| A 083 | Continued From page 109<br><br>During an interview on 3/24/21, at 2:35 PM, with Emergency Department Physician (MD 6), MD 6 stated "syringes were found in his [SC 1] pockets".<br><br>During a concurrent interview and review of the video footage, on 3/26/21 at 10:18 AM and 3/30/21, at 3:30 PM, with Security Services Manager (SSM), SSM stated on 12/22/20 at 12:34 AM, SC 1 was observed entering Patient 1's room, room 19. Near the door, SC 1 was opening a drawer containing syringes and the drawer above it containing needles, and next SC 1 discarded a wrapper of a needle in the trash. There was a RN in the room, who could not be identified. At the room entry the Emergency Department Technician (EDT) and Environmental Services (EVS) staff are tending to the trash.<br><br>During an interview on 3/29/21 at 7:05 PM, with Emergency Department Physician (MD 7), MD 7 stated SC 1 was found in the ED public bathroom with "needles" and "big syringes, 60 ml" of Propofol.<br><br>During an interview on 3/29/21, at 8:15 PM with the Security Officer (SO 1) SO 1 identified individuals in the video and were later confirmed by Emergency Department Nurse Manager (EDNM).<br><br>During the Governing Board Meeting on 4/1/21, at 12:20 PM, the Chief Nursing Officer (CNO) stated, she was "aware" of episodes of syringes and needles in the ED bathrooms in December 2020. CNO stated, "took a rapid approach ...interventional approach" for needles and syringes and there is an "investigation." | A 083 | | |

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| A 083 | Continued From page 110<br><br>During the Governing Board Meeting on 4/1/2021, at 12:25 PM, the CEO stated he was unaware of the syringes and needles found in the emergency department.<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated, "1. When suspicious patterns of activity or other reasonable cause to suspect f=drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion". (Hospital followed all of this except MBC)<br><br>During a review of the electronic mail the Director | A 083 | | |

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of Risk Management (DRM), dated 2/2/21 at 2:25 PM, the email indicated, "To: [Facility] Urgent, Subject: Drug Diversion Prevention. Drug diversion is a term used when an individual removes, takes, or find medication) s) that ate prescribed for someone else and used them for him/herself. Examples: A patient is prescribed two pills - the person gives one pill to the patient and keeps one pill for themselves ... person uses an empty syringe to remove medicine from an IV tubing to inject into themselves ...A person finds medication and takes it home ... What are suspicious findings or signs of drug diversion? Syringes or empty medication containers found in trash, bathroom, on counters, or other non-patient care areas ...Blood and blood products in the trash in patient care setting not infusing ...Syringes, needles, or medications being kept in unsecure locations ...Count discrepancies ...uncontrolled patient pain ...Reporting findings is for the safety and well-being of everybody. Reporting suspicious findings can potentially save a life and prevent harm. For information see Policy HR 200". One of the pictures used in the email, appear to be similar to MIDAS report

During a review of the hospital's P&P titled, "Clinical Information Assistant /Scribes in the Emergency Department," (ED 1013), dated 2/09/18, the P&P indicated, "Emergency Department (ED) allows the use of Scribes [secretary transcriber of information] to support patient flow in the department while under the direct supervision [physician must be present at all times] of the medical provider. The scribe may not function independently at any time in the ED...While in the patient care environment, the scribe will be under the direct supervision of the

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assigned emergency medical provider...The scribe shall accompany the medical provider into the exam room and transcribe the patient's history, physical exam and any laboratory and radiology results as dictated by the medical provider...The scribe cannot provide any direct hands-on patient care...The scribe may not enter any orders, all order entries are the responsibility of the medical provider."

During a review of the Physician Contract Agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department," dated 8/20/20, the physician contract agreement indicated "Medical Group shall at all times comply with bylaws, rules and regulations, policies and directives of the [Facility] and the Medical Staff.. Compliance Program. Medical Group will comply with all [Facility] policies, procedures, and code of conduct. The agreement indicated, the "Medical Group and its personnel shall document exclusively in the electronic medical record...If Medical Group uses scribes, who are not clinical staff, Medical Group shall be entirely responsible for such scribes, and ensure that they follow all policy and procedures of the [Facility], and all relevant laws and regulations."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, the P&P indicated, "Providers are to refrain from delegating responsibility for hospitalized patients to any individual who is not qualified or adequately supervised (Scribe, Resident [a physician who has finished medical school and is training in a specific area]); to refrain from deceiving patients as to the identity of any individual providing treatment or services".

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3. During an interview on 3/23/21, at 6:15 PM, with RN 2, RN 2 stated in addition to SC 1, he was aware of episodes of used syringes and needles, with evidence of a "white milky substance, Propofol".

During an interview on 3/23/21, at 8:30 PM, with RN 3, RN 3 stated, in addition to SC 1, on three separate occasions, she found contaminated syringes and needles, alcohol swabs, and sometimes blood in the ED bathrooms. She stated the syringes had "white substance ...looked like Propofol" in them. RN stated she reported the episodes to RN 16. RN 3 stated, RN 16 notified the House Supervisor (HS) of the findings.

During an interview, on 3/25/21, at 8:50 PM, with RN 1, RN 1 stated, "Syringes were found in a bathroom with white substance in them, not the bathroom SC 1 was found in..., and during the code [resuscitation] we found more syringes". RN 1 stated, she "noticed Propofol was missing" from Patient 1. RN 1 stated this triggered, her, RN 2, RN 3, RN 14 all to look for SC 1. RN 1 stated RN 3 said "we need to find him [SC 1], before he is dead."

During an interview on 3/26/2021, at 10:18 AM with Security Officer (SO 1), SO 1 stated he wrote a report regarding the 12/22/2020 events of SC 1, and was given new information regarding syringes and needles found in ED bathrooms over the prior days. The report indicated "during the investigation staff members found syringes with a milky white substance, alcohol wipes, and blood in the staff restroom outside of Zone 3 that night and the night prior. The nursing staff were

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concerned a staff member was potentially using drugs in this location." SO 1 stated these incidents were not reported to security department. SO 1 stated, there are "no policies" if syringes are found on [Facility] grounds ...bathrooms, parking lot, sidewalk ... if syringes are found...glove-up, pick it up and throw it in the sharp container...no logs of syndromes [are kept]".

During an interview on 3/26/21 at 6 PM, with Security Officer Supervisor (SOS 1), SOS 1 stated he did not take the [Facility] security report on 12/22/21 regarding SC 1, but there was a "similar episode" the night before, on 12/20/20. It occurred in "Zone 3" where there are no cameras, "needles and syringes were found in the bathrooms". SOS 1 stated security "should be notified of all events regarding illegal substance and suspicious substances" on hospital grounds. SOS 1 stated he did not have a report for the event.

During an interview on 3/29/21, at 7:05 PM, with Emergency Department Physician (MD 7), MD 7 stated "housekeeping found syringes" in a staff ED bathroom, and clarified "not the bathroom [SC 1] was found in." MD 7 stated the events were reported to the charge nurse, RN 3. MD 7 stated, staff was "concerned SC 1 was involved". On 12/22/20, MD 7 stated SC 1 was found in the ED public bathroom. MD 7 stated "needles" and "big syringes, 60 ml" of Propofol were found.

During an interview on 3/31/21, at 3:40 PM, with HS, HS stated environmental services (EVS) staff notified him of blood and used needles and syringes in a "secure area staff [ED] bathroom" HS stated EVS reported the episodes to security,

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ED team lead, ED nurses who in turn notified him. HS stated "it must be staff". HS stated he could not recall the day of the events and did not complete an occurrence report.

During a review of the electronic mail, titled "Urgent Message Drug Diversion Prevention," dated 2/8/21 at 2:25 PM, from the Director of Risk Management (DRM), provided by Risk Management, the email included a picture from Environmental Services Manager (EVSM) report and ways to prevent and report "suspicious findings or signs of drug diversion" "for the safety and well-being of everybody ...You can save a life". The email was sent to "District", but unclear who the email was sent to.

During an interview on 3/21/21, at 2:50 PM, with the Director of Environmental Service/ Laundry and Environmental Service Manager (DEVS) and EVSM, DEVS stated we received reports from EVS (environmental service) staff that syringes with a white liquid/blood, dirty used syringes, needles and/or paper were found in the ED staff bathroom. DEVS stated he recalls one email regarding these episodes, and forwarded them to Risk. EVMS stated the process for any item of concern or illegal drug use at [Facility], EVS staff is to call security and communicate with management. DEVS and EVSM stated MIDAS (a system for healthcare workers to report near misses and patient safety concerns) reports were not completed for any of the events.

During a review of the electronic mail (email), dated 12/22/20 at 8:04 AM, the email with attached photo included email communication between DRM, DEVS, Chief of Human Resources (CHRO) and Emergency Department

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Nurse Manager (EDNM). The photo content of the email had used syringes, wrappers and blood in an ED bathroom found by EVS staff. The email indicated EVS staff identified used syringes, wrappers, and blood, "found yesterday morning", and "it was also said seen again this morning." The email indicated, CHRO wrote "another employee overdosed in a bathroom last night, but thinking it would have been another location." DEVS wrote, "Will follow-up with another staff member who also saw a syringe (not sure if it was the same location as yesterday morning)". DEVS could not determine how many syringes and needles were found and on what days. No occurrence reports were written and there were no other email exchanges.

During the Governing Board meeting on 4/1/2021 at 12:20 PM, the CEO stated he was not aware of the episodes of used syringes and needles in the ED bathrooms.

During the Governing Board Meeting on 4/1/2021 at 12:20 PM, the Chief Nursing Officer (CNO) stated, she was "aware" of episodes of syringes and needles in the ED bathrooms in December 2020. CNO stated "took a rapid approach...interventional approach" for needles and syringes and there is an "investigation".

During a review of the email, dated 2/8/21, at 2:25 PM, from DRM, the email indicated, "To: [Facility] Urgent, Subject: Drug Diversion Prevention. Drug diversion is a term used when an individual removes, takes, or find medication) s) that ate prescribed for someone else and used them for him/herself. Examples: A patient is prescribed two pills - the person gives one pill to the patient and keeps one pill for

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themselves...person uses an empty syringe to remove medicine from an IV tubing to inject into themselves ...A person finds medication and takes it home. . .What are suspicious findings or signs of drug diversion? Syringes or empty medication containers found in trash, bathroom, on counters, or other non-patient care areas. Blood and blood products in the trash in patient care setting not infusing... Syringes , needles , or medications being kept in unsecure locations...Count discrepancies...uncontrolled patient pain...Reporting findings is for the safety and well-being of everybody. Reporting suspicious findings can potentially save a life and prevent harm. For information see Policy HR 200". One of the pictures used in the email, appear to be similar to the MIDAS report.

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect f=drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be

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considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion".

During a review of the hospital's policy and procedure (P&P) titled, "Occurrence Reporting Process," (AP 10), dated 8/26/19, the P&P indicated, "Occurrences unusual or unexpected event, which may result in actual or potential harm to patients, staff members, or [Facility] visitors... adverse drug event a 'variant related to the use of omission of a drug as well as 'close calls' or 'safe catches.' Statement of Concern 'an event related to an unresolved interpersonal (behavioral) issue.' The Occurrence Reporting process also encompasses unresolved behavioral issues...Statement of Concern: reporting, compliant and grievance reporting and ADE [adverse drug event] reporting: When an incident or unusual event occurs the individual most familiar with the situation...shall complete the Occurrence Reporting form. The form will be submitted to the RM (Risk Management) within 5 days of the event, or at the time in which the event is discovered...Staff will telephone the RM Department of any unusual event, which results in patient injury immediately..."

During a review of the hospital's P&P titled, "Dangerous Drugs: Theft/Loss", (KDEP 11), dated 6/19/19, the P&P indicated and "outlined the proper procedure in the case of theft/loss of controlled substance, chemicals listed in the

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Department of Justice Manual ("List 1 Chemicals, substances regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other dangerous drugs ...Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft/loss in transit...Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and /or other law enforcement agency. 6. California Department of Public Health."

During a review of the hospital's P&P titled, "Drug Free Work Place and Drug/Alcohol Testing", (HR 200), dated 4/29/20, the P&P indicated the "[Facility] has established this policy on the use or abuse of alcohol and illegal drugs or other controlled substances by employees, contract staff or volunteers. At work or otherwise, substance abuse seriously endangers the safety of the work environment, as well as our patients and the general public. The [Facility] has

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established this policy to detect users and remove abusers of drugs and alcohol and to prevent the use and/or presence of these substances on the workplace. Confirmed incidents of drug diversion will be reported to the appropriate agencies...[Facility] may suspend employees without pay under this policy pending the results of a drug test or investigation...'Illegal drugs or other controlled substances' means any drug or substances that is not legally obtainable; or is legally obtainable but has not been legally obtained; or has been legally obtained but is being sold or distributed unlawfully... 'Abuse of any legal drug' means the use of any legal drug: for any purpose other than the purpose for which it was prescribes or manufactured...'Reasonable suspicion includes suspicion that is based on specific personal observations...information provided to management by an employee, by law enforcement officials, or by other persons believed to be reliable; or suspicion based on other surrounding circumstance...'Drug diversion' means that an employee has the substance on his or her person or otherwise under his or her control...Drug Use Prohibitions: violation of following will result in reporting the employee to a licensing board or agency, law enforcement agencies and /or /disciplinary action , up to and including termination of employment. The Director of Pharmacy or designee will determine the necessity of reporting to Drug Enforcement Agencies, the California Board of Pharmacy and Police. Human resources will report employee's licensing or certifying board as necessary. The Risk Management department will report to the California Department of Public Health as appropriate. 1. The unlawful use, sale, purchase, possession, manufacture, distribution, or dispensation of any drug or prescribed controlled

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substance on property or during work time is against policy...Testing of Current Employees: Employees must submit to a drug test if reasonable suspicion exists...Reasonable suspicion testing means drug testing based on a belief that an employee is using or has used drugs in violation of [Facility] policy. Among other things, such facts and inferences may be based upon: Direct observations...abnormal conduct...a report of drug use, provided by a reliable and credible source...evidence that an employee has used, possessed, sold, solicited or transferred drugs while working or on[Facility] premises or while operating [Facility] vehicles, machinery or equipment...Audit findings or charting issues...Actions to be taken by Management: There may be instance where supervisors /managers have reasonable cause to believe that employee consumed drugs on [Facility] premises or reported to work under the influence of one or both. In these instances management may request drug tests. . .If the employee refuses to sign the consent [for drug testing] or provide a sample, he/she will be subject to Disciplinary action up to and including termination of employment...Drug-Free contract and follow-up testing: As a condition of employment and /or continued employment, participants in a rehabilitation program for drug and/or alcohol abuse must consent in writing via a [Facility] Drug-Free Contract to periodic unannounced testing for a period up to two (2) years after returning to work".

During a review of the hospital's P&P titled, "Suspected Illegal Substances", (AP 139), dated 1/29/20, the P&P indicated the [Facility] follows the federal government Controlled Substance Act of 1970 (CSA) and defined "illegal substance [as]

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illegal drugs are substances, which individuals, by law, is not allowed to possess, use or distribute". "[Facility] is entrusted with the responsibility of providing quality care and a safe, healthy, and efficient working environment...if [Facility] staff members accidentally find any unusual substance which they suspect might be illegal drugs, staff are to notify their manager, [Facility] security, and Risk Manager immediately. . .staff will provide the substance to Security staff...Security will notify [local] police...Security will provide the substance to the [Police] upon arrival...[Police] will take possession of the illegal substance...[Police] may write a crime report...Security will prepare a Security Department Incident Report and forward to risk management."

During a review of the hospital's P&P titled, "Reporting Requirements for Drug diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect for drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be considered confirmed if after investigation there is: An admission of guilt by the person suspected;

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| A 083 | Continued From page 123<br>Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion". (Hospital followed all of this except MBC)<br><br>During a review of the hospital's P&) titled, "Personnel Management: Public Protection & Reporting Requirements", (KDEP 15), dated 11/10/14, the P&P indicated "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or her license will be addressed promptly. The policy outlined procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it effects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs...in the interest of protecting the public, follows established procedures: Human Resource Policy HR 200, 'Drugs and Alcohol"; Administrative Policy AP 110, "Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse", and Reporting to the California Board of Pharmacy within 14 days of receipt or development of the following information with regards to any licensed individual employed by or with the pharmacy": theft, diversion, or self-use of dangerous drugs, physical or mental impairment." | A 083 | | |
| A 084 | CONTRACTED SERVICES | A 084 | | |

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| A 084 | Continued From page 124<br>CFR(s): 482.12(e)(1)<br><br>The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Governing Body failed to ensure the Emergency Department (ED) Staff were informed of the duties, responsibilities, and restrictions for one of one unauthorized contract staff, Scribe (SC 1- a person who performs patient documentation and clerical tasks on behalf of a physician). This failure resulted in SC 1's easy access to ED supplies (needles, syringes, alcohol swabs), which subsequently resulted in SC 1 having access to Patient 1's Propofol (a strong anesthesia medication used to provide unconsciousness and sedation, and the inappropriate use can lead to death) hanging on the Intravenous (IV) pole , which was detrimental and caused harm to SC 1.<br><br>Findings:<br><br>During an interview on 3/22/21, at 10:50 AM, with the Graduate of Medical Education Program Director, Emergency Department (MD 9), MD 9 stated, physician scribes are employees of the Emergency Department Medical Group contracted to the hospital. The scribes are not employees of the hospital. The scribes follow the physicians around. They cannot be in the patient's room without the Provider. They sit next to the physician or the Resident (a physician who has finished medical school and is training in a specialized area or a medical specialty). The only time they are not with the Provider or Resident is | A 084 | | |

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during lunch/dinner time. They work six to eight hours in the ED and they are assigned to a Team of Physician and Residents. They are not allowed to touch the patients. They are not allowed to perform any other services other than working with Physicians or the Residents.

During an interview on 3/22/21, at 11 AM, with the Emergency Department Nurse Manager (EDNM), EDNM stated, the nurses do not provide oversight for the scribe. EDNM is not aware of any hospital or departmental orientation provided to the scribes.

During a review of Patient 1's Medication Administration Record (MAR), dated 12/21/22, the MAR indicated, Propofol 2000 mg (milligrams, a unit of measure) in 100 ml (milliliter (a unit of measure) at 5 mcg/kg/min ("mcg' microgram per "kg" kilogram, per minute) IV (intravenous -into vein) infusion. Registered Nurse (RN 1) started the infusion for Patient 1 in Room 19, at 10:07 PM, but was stopped two minutes later at 10:09 PM because Patient 1 had no blood pressure.

During an interview on 3/25/21, at 8:50 PM, with RN 1, RN 1 stated, Propofol was left "hanging on the IV pole", for up to 6 hours and still connected to Patient 1 in Room 19. The bottle is not secured to prevent others from accessing it. RN 1 stated when she was disconnecting Patient 1's Propofol infusion, she "noticed 3/4 of the bottle was empty" and she spoke with RN 3 and the Clinical Pharmacist Emergency Department (RPHED) about the missing Propofol. RN 1 stated when she reported the event, "something clicked" about not being able to find SC 1 for several hours. RN 1 stated, RN 3 was concerned and RN 3 said "we need to find [SC 1] before he is dead".

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During an interview on 3/30/21, at 8:15 PM, with RN 3, RN 3 stated, Propofol was placed on "pause" because Patient had no blood pressure and may "restart" later if necessary; thus, Propofol was "left hanging and attached to Patient 1" for several hours. T he bottle is not secured to prevent others from accessing it.

During a concurrent interview and review of the video footage of the incident, on 3/26/21, at 10:18 AM, with Security Services Manager (SSM), SSM stated, per the video footage, SC 1 was observed entering Patient 1's room, room 19. Near the door, SC 1 opened a drawer containing syringes and a drawer above it containing needles. A needle wrapper was discarded in the trash.

During an interview on 3/23/21, at 6:15 PM, with Registered Nurse (RN 2) RN 2 stated, there was a debriefing and we were asking where the Propofol came from-rooms 19, 20, and 25 ...rooms that had Propofol infusing for patients". RN 2 stated SC 1's behavior had "been different ...suspicious ...everyone knew what he was up to."

During an interview on 3/29/21, at 7:05 PM, with Emergency Department Physician (MD 7), MD 7 stated, Patient 1 in room 19 was on "comfort care" and RN 1 noticed "the Propofol bottle was emptier than they should have been ...there were obvious clues of what was taken ...room 26 was on Propofol and there were concerns Propofol was taken from this patient also".

During an interview on 3/29/2021 at 8:15 PM, with Security Officer (SO 1), SO 1 stated, during the debriefing, RN 3 informed him that "she believed

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[SC 1] gained access to the drug by filling two syringes with Propofol container that was meant to be given to a patient in room 19 of the ED and then he went inside Zone 1 restroom where he ultimately injected himself with the drug".

During an interview on 3/26/21 at 2:45 PM, with Detective, Tulare County (DET), DET stated the ED staff informed him "a couple of syringes were found with [SC 1]". He stated he was informed it was "Propofol" and the medication "was short on another patient".

During the Governing Board Meeting on, 4/1/21 at 12:20 PM, Chief Nursing Officer (CNO), acknowledged she was aware of "Propofol" being obtained from patients' IV lines in the ED.

During the Governing Board Meeting on, 4/1/21 at 12:20 PM, Chief Executive Officer (CEO) stated, the events of "Propofol" being obtained from patients' IV lines in "environment that allowed it" is concerning.

During a review of the hospital's policy and procedure (P&P) titled, "Personnel Management: Public Protection & Reporting Requirements, " (KDEP 15), dated 11/10/14, the P&P indicated, "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or her license will be addressed promptly."

During a review of the hospital's P&P titled, "Dangerous Drugs: Theft/Loss", (KDEP 11), dated 6/19/19, the P&P indicated , and "outlined the proper procedure in the case of theft/loss of controlled substance, chemicals listed in the

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| A 084 | Continued From page 128<br>Department of Justice Manual ("List 1 Chemicals, substances regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other dangerous drugs ...Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft ...loss in transit ...Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and /or other law enforcement agency. 6. California Department of Public Health."<br><br>During a review of the hospital's P&P titled, "Reporting Requirements for Drug Diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect of drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk | A 084 | | |

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Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion". (Hospital followed all of this except MBC)

During a review of the hospital's P&P titled, "Clinical Information Assistant /Scribes in the Emergency Department", (ED 1013), dated 2/09/18, the P*P indicated Emergency Department (ED) allows the use of Scribes [secretary transcriber of information] to support patient flow in the department while under the direct supervision [physician must be present at all times] of the medical provider. The scribe may not function independently at any time in the ED ...While in the patient care environment, the scribe will be under the direct supervision of the assigned emergency medical provider ... The scribe shall accompany the medical provider into the exam room and transcribe the patient's history, physical exam and any laboratory and radiology results as dictated by the medical provider ... The scribe cannot provide any direct

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| A 084 | Continued From page 130<br>hands-on patient care ...The scribe may not enter any orders, all order entries are the responsibility of the medical provider."<br><br>During a review of the physician contract agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department", dated 8/20/2020, the policy indicated, "Medical Group shall at all times comply with bylaws, rules and regulations, policies and directives of the [Facility] and the Medical Staff ...Compliance Program. . if the Medical Group uses scribes, who are not clinical staff, Medical Group shall be entirely responsible for such scribes, and ensure that they follow all policy and procedures of the [Facility], and all relevant laws and regulations".<br><br>During a review of the hospital's P&P titled "Medical Staff Bylaws", dated 12/21/20, the P&P indicated, "Providers are "to refrain from delegating responsibility for hospitalized patients to any individual who is not qualified or adequately supervised (Scribe, resident); to refrain from deceiving patients as to the identity of any individual providing treatment or services". | A 084 | | |
| A 130 | PATIENT RIGHTS:PARTICIPATION IN CARE PLANNING<br>CFR(s): 482.13(b)(1)<br><br>The patient has the right to participate in the development and implementation of his or her plan of care.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Hospital failed to ensure one of one sampled patient (Patient 1) participated in the | A 130 | | |

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implementation of his plan of care. This failure resulted in Patient 1 not given the opportunity to make decisions about his care, which negatively affected health care outcomes.

Findings:

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, the History of Present Illness indicated, Patient 1 arrived via ambulance at 6:56 PM in the Emergency Department (ED). Prior to arrival to the ED Patient 1 had a respiratory rate of 32 (normal breathing 12 to 18 breathes per minute), oxygen saturation of 67% (also known as SP02, which signals the amount of oxygen in one's blood, normal is 95% to 100% ), blood pressure of 138/60 (average normal is 120/80), sinus tachycardia (heart beating faster than normal, normal is 60 to 100 beats per minute), GCS 15 (Glasgow Coma Scale/Score numeric ranking of 0 to 15 points for speech, movement and alertness. 15 points highest possible reflecting no problems), shortness of breath, can utter two-three word sentences, and cyanosis (blue colored skin due to lack of oxygen). Patient 1's Emergency Documentation also indicated, Registered Nurse (RN 1) and Respiratory Therapist (RT 1) "advocated for intubation" for Patient 1 many times because Patient 1 was "critically ill. . ."in respiratory distress". . ."had an SPO2 of 64% on room air."

During an interview on 3/25/21, at 8:23 PM, with Registered Nurse (RN) 1, RN 1 stated, Patient 1 was "critically ill" and she was "in and out of the room, "advocating many times" for Patient 1's intubation and spoke with Emergency Department PGY 1 Resident 1 (a physician in

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training) Resident 1 and Emergency Department Physician (MD 5), who was the Attending/Supervising Physician on-duty. RN 1 stated, Patient 1 was having a "hard time breathing. . .not improving. . .difficult getting oxygen saturation up [oxygen level from SP02 monitor] . . ."patient couldn't breathe."

During an interview on 3/25/21, at 7:05 PM, with Respiratory Therapist (health professionals who specialize in respiratory care, handling breathing and airway problems) (RT) 1, RT 1 stated, "Patient 1 asked for breathing tube ... voicing 'can't breathe' and struggling". For several hours, RT 1 stated, Patient 1 was in distress ...deteriorating ...desating [desaturation, oxygen levels falling below normal] ...BiPAP (Bi-level Positive Airway Pressure - a machine that pushes air into the lungs to assist with breathing) didn't work and not tolerated". RT 1 stated admission laboratory findings were "horrible". RT 1 stated on Patient 1's behalf "advocated multiple times" and discussed intubation with Resident 1 and MD 5. RT 1 stated RN 1 was doing the same.

During an interview on 3/23/21, at 3:46 PM, with MD 5, MD 5 stated he did not intubate Patient 1 on arrival because it was a "judgement call", but during a "reassessment [MD 5] talked [to Patient 1] about intubation while on BiPAP. Although the patient requested to be intubated and the nurses and RT advocated on Patient 1's behalf, MD 5 stated he did not document the reassessment and did not intubate.

During a concurrent interview and record review, with ED Resident PGY 3 (Resident 3) on 3/23/2021 at 8:35 PM, and 8:48 PM, the medical record indicated a patient assessment by

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Resident 1: Patient 2 stated, "prefer intubation to BiPAP". At 10:02 p.m., Resident 1 documented in the chart, Patient 2 "persistently unable to tolerate BiPAP and was intubated.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, "The responsibility of the attending physician, he/she will be responsible for the medical care and treatment of the patient while in [Facility]. . .prompt and accurate completion of portions to the medical record for which he or she is responsible. . .performing all other duties described in these Rules and Regulations. At all times during the patient's hospitalization, the identity of the attending physician will be clearly documented in the medical record. "Progress notes: Clinically pertinent progress notes shall be recorded at the time of observation, and must be legible, dated, and timed, shall be documented with a frequency consistent with the acuity of medical problems to reflect patient's condition and plans for management, and shall always be written in a manner with such clarity and frequency that another Practioner could quickly understand the [patient's status. . .Any complications must also be documented.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/2020, the P&P indicated, "The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in [Facility]. . .prompt and accurate completion of portions to the medical record for which he or she is responsible. . .performing all other duties described in these Rules and Regulations. At all

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times during the patient's hospitalization, the identity of the attending physician will be clearly documented in the medical record. All Medical Records for patients receiving care in the hospital setting or at an ambulatory care location will include the information outlined in this section as relevant and appropriate to the patient's care. Examples include identification, legal status, language, informed consent, records of communication, emergency care, admitting history, allergies, reason for admission, diagnosis, diagnostic impression, medication orders, consultation reports, response to care, treatment and services provided, observations, and reassessments. Progress notes: Clinically pertinent progress notes shall be recorded at the time of observation, and must be legible, dated, and timed, shall be documented with a frequency consistent with the acuity of medical problems to reflect patient's condition and plans for management, and shall always be written in a manner with such clarity and frequency that another Practioner could quickly understand the [patient's status. . .Any complications must also be documented."

During a review of the hospital's policy and procedure (P&P) titled, "Code of Conduct for Medical Staff & Advanced Practice Providers" (MS 47), dated 1/30/19, the P&P indicated, "Practitioners have a responsibility for the welfare of their patients. . .The safeguarding of patient care and safety is paramount, and the Medical Staff will enforce this policy with disciplinary measures whenever necessary. Examples of inappropriate behavior means conduct that is unwarranted and reasonable interpreted to be demeaning or offensive. or blatant failure to respond to patient care needs or staff requests."

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| A 130 | Continued From page 135<br><br>During a review of the Physician Contract Agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department", dated 8/20/2020, indicated, the "Medical Group shall and shall require all Medical Group Personnel to : provide services under this Agreement in accordance with appropriate standards of clinical practice, all applicable federal and state laws and regulations, all applicable rules in regulations of the Medical Board of California, and the Standards of the American Board of Emergency Medicine ...Comply with all applicable medical staff bylaws, rules, regulations, policies and procedures of the[Facility], including code of conduct and conflict of interest policies and procedures ...Comply with all applicable<br><br>During a review of the hospital's policy and procedure (P&P) titled, "District Bylaws" for [Facility], dated 4/27/20, the P&P indicated the "Governing Body shall address issues related to quality patient care regularly". | A 130 | | |
| A 132 | PATIENT RIGHTS: INFORMED DECISION<br>CFR(s): 482.13(b)(3)<br><br>The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Medical Staff and providers failed to follow | A 132 | | |

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advance directive procedures for full code status (all necessary medical interventions to sustain life) and medical support for one of one sampled patient (Patient 1). This failure resulted in Patient 1's full code directives being changed from full code to "comfort care (end of life care)", and withdrawal of medical care against Patient 1's wishes.

Findings:

During a review of Patient 1's "Emergency Documentation" dated 12/21/20, the ED notes indicated, "Between 7:01 PM and 9:44 PM, Patient 1 was "critically ill...in distress".The chart (medical record) indicated Patient 1 was a full code. At 10:37 PM, Patient 1 "had a wide complex tachycardia [life threatening malfunction of heart beats] on the monitor and lost pulses which was witnessed by Registered Nurse (RN 1) and Emergency Department Resident PGY 1 (Resident 1 physician in training). Cardiopulmonary resuscitation (CPR- [life sustaining efforts] were initiated. . .and ROSC [return of spontaneous circulation] was achieved. On 12/22/21, between 12:42 AM and 1:41 AM, the chart indicated, Patient 1, who was intubated, on a ventilator, and waiting to be admitted to the Intensive Care Unit (a clinical area in the hospital where critical patients are cared for), full code status was changed to "comfort care" (comfort measures and no medical interventions to save a person's life). Neither, the ED attending/supervising physician (MD 5 or Resident 1 documented an assessment to determine Patient 1's viability or signs of life, or a reason to withdraw medical care. There was no documentation of vital signs or assessment of Patient 1 by MD 5, Resident 1, Respiratory

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Therapist (RT 1) or RN 1. There was no documentation of vital signs, temperature, cardiac monitoring, oxygen delivery, ventilator use, ECG (heart function tracing), reflexes, apnea test (test to determine if a person can breath without help), examination of the heart, lungs and nervous systems, or normal laboratory values. There were no documented orders, Physician Order for Life Sustaining Treatment (POLST-life directives stating for wishes for full resuscitation, partial resuscitation, no code or natural death, and it must be signed by patient and/or patient representative and physician) form, neurology (physician who evaluates the brain and nervous system) consult or palliative care consult (medical care that provides relief from pain & other distressing symptoms).

During a concurrent interview and record review, on 3/25/21, at 6:15 PM, with RN 1, Patient 1's ED notes dated 12/21/2020 to 12 /22/2020 indicated, Patient 1 was a "full code", with Glasgow Coma Score (GCS- index for evaluating the level of consciousness, numeric ranking of 0 to 15 points for speech, movement and alertness. 15 points highest possible reflecting no problems] of 15, alert and oriented, following commands, no neurologic deficits, and able to make decisions". RN 1 verified the findings.

During a concurrent interview and record review, on 3/23/21, at 8:35 PM, with Resident 1, Patient 1's ED notes dated 12/21/2020 to 12 /22/2020 were reviewed. The ED notes indicated, Patient 1 was a full code. Resident 1 "confirmed" Patient 1 was a "full code". Resident 1 acknowledged he did not speak with the family or patient representative regarding changing Patient 1's status from full code to "comfort care". Resident

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1 stated he "believes" MD 5 spoke with the family about "comfort care" and "patient status". Resident 1 did not speak with MD 5 regarding Patient 1's code status, nor did he document any communications with the MD 5, his supervising physician.

During a concurrent interview and record review, on 3/23/21, at -- with MD 5, Patient 1's ED notes dated 12/21/2020 to 12 /22/2020 were reviewed. The ED notes indicated, on arrival to the ED Patient 1 was a "full code ...GCS 15 [Glasgow Coma Scale/Score alert and oriented [knew who and where he was, and why he was at the hospital] ...good decision making ability". MD 5 verified the findings. MD 5 stated he spoke with the sister on 12/21/20 at 11:19 PM and per documentation, "relayed patient's critical condition and difficult prognosis". MD 5 stated he "recalls" Patient 1's wishes to be a "full Code", but "can't recall" how the "full code" was changed to "comfort care". MD 5 stated, "Resident 1 was "taking care of Patient 1".

During a concurrent interview and record review, on 3/25/21, at 7:05 PM, with Respiratory Therapist (RT 1), Patient 1's ED notes dated 12/21/2020 to 12 /22/2020 were reviewed. Patient 1's ED notes indicated, Patient 1 was a full Code, with GCS of 15. RT 1 verified the findings. RT 1 acknowledged she did not chart any care that she provided to Patient 1. RT 1 stated, she recalled Patient 1 had a GCS of 15, was alert and oriented, answered questions appropriately and followed commands. RT 1 stated, Patient 1 was a "full code", until a physician "placed him on comfort care.".

During an interview on 3/29/21, 6:17 PM, with

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Critical Care Physician (MD 18) , MD 18 stated he spoke with Resident 1 and was "surprised the resident made Patient 1 'comfort care'". MD 18 stated he was not informed as to why Patient 1's status "changed" from a full code, after a successful ROSC, and pending ICU admission to "comfort care". MD 18 stated the ICU team consulted on Patient 1, but he was never transferred to the ICU. MD 18 stated, he "did not have answers" and there was "no documentation". MD 18 stated Patient 1 was a full code, and he "would have not made Patient 1 comfort care unless family shows proof of Direct Power Of Attorney (DPOA -person who has the power to make decisions for the patient) and document before considering" changes. MD 18 stated if a patient is a "full code "and there is "consideration for comfort care" and reasons to withdrawal of medical care, there are "protocols". MD 18 stated he "would not have made any decision about comfort care on a full code".

During an interview on 3/24/21, at 2:35 PM, with ED Physician (MD 6), MD 6 stated he does not know how a patient would progress from a full code, after successful ROSC, and pending ICU admission to "comfort care" and withdrawal of medical care.

During a concurrent interview and record review, on 3/29/21, at 7:05 PM, with ED Physician (MD 7), Patient 1's ED notes dated 12/21/2020 to 12 /22/2020 were reviewed. MD 7 agreed with the documentation. MD 7 stated he did not know how Patient 1 went from a full code, successful ROSC, and pending ICU admission to "comfort care". The chart (medical record)reflected that MD 7 was assigned to and took over the care of Patient 1, and documented a physician hand-off

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from MD 5. The sign-out indicated MD 5 placed Patient 1 on "comfort care". MD 7 acknowledged he "did not read the chart" or "consult" with MD 18 regarding Patient 1's care plans or code status. MD 7 stated he "received second hand information about Patient 1's code status". MD 7 reviewed the chart and stated, Patient 1 was a full code, alert and oriented, GCS of 15 and no deficits, but did not know why Patient was made "comfort Care" or reasons to withdrawal of medical care.

During a review of the hospital's policy and procedure (P&P) titled, "Resuscitation Status: Ordering Appropriate (OARS) (PC 238), dated 6/22/18, the P&P indicated, "OARS recognizes the patient's goal for care and match interventions to those goals. . ..OARS interventions consist of Full Resuscitation [full efforts and interventions taken to save the patient's life], Limited Resuscitation of which limitations must be noted in the order, Comfort Care consult, and Palliative care consult. . .provide continuing care to the patient consistent with the patient's health care instructions until transfer can be accomplished. When consent is received from someone other than the patient, the physician shall document the identity of that individual, the legal status of the individual".

During a review of the hospital's policy and procedure (P&P) titled, "Do not Resuscitate (Resuscitation Status), (PC 217), dated 1/10/20 the P&P indicated, "Advance Directive is a legal document describing a patient's medical treatment decisions and end of life decisions and or designation of a surrogate decision-maker for health care decisions . . .Advance Directives are governed by California Probate Sections 4700 et

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| A 132 | Continued From page 141<br>seq. . .Physician Orders for Life Sustaining Treatment (POLST) provide a mechanism to communicate patient preferences for end-of-life treatment [full treatment to limited treatment to natural death] across treatment settings and the preferences be followed. . ..must be signed by a physician. . .It complements but does not replace Advance Directives. . .Absence an Advance Directive efforts will be made to honor the patient's stated wishes".<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Brain Death Patient, Physician Determination of , and Family Accommodations", (PC 220), dated 12/1919, the P&P indicated, "A determination of death must be made in accordance with acceptable medical standards When an individual is pronounces dead by determining that the individual has sustained an irreversible cessation of all functions of the entire brain ...there should be independent confirmation by another physician as required by California Statue (Health and Safety Code Section 7181). . .The American Academy of Neurology (AAN) published practice parameters to delineate the medical standards for determination of brain death. The AAN parameters emphasized that three clinical findings necessary to confirm irreversible cessation of all functions of the brain, including the brain stem are: coma, absence of brainstem reflexes and apnea. . .when there is suspicion that brain death may have occurred, a clinical examination and confirmatory testing for brain death is done. An independent confirmation of brain death by a second physician is required by law. . .Prerequisite clinical findings which must be established prior to examination for brain death. . .the cause of coma must be identified and | A 132 | | |

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irreversibility established by history, examination, neuro-imaging or other tests. . .Absence of CNS depressant drug effects. . .drug screen. . .serum drug levels below therapeutic levels. . .alcohol level below 0.8%. . .absence of neuromuscular blocking agents. . ..absence of sever electrolyte imbalance, acid-base or endocrine imbalance, as evidenced by laboratory data. . .normal core temperature".

During a review of California State and Federal Regulations, the Regulations indicated, "Determine death of patient-- Uniform determination of Death act UDDA, approved for the United States in 1981 when an individual may legally be declared dead ... and Health Safety code State of California Chapter 3 section 7180 et., (a) An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards... (c) This article may be cited as the Uniform Determination of Death Act. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=7180. Accessed 4/24/2021.

During a review of the "Uniform Determination of Death Act (UDDA"the Act indicated, "It is a "model state law that was approved for the United States in 1981 by the National Conference of Commissioners on Uniform State Laws, in cooperation with the American Medical Association, the American Bar Association, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research". The act has since been

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adopted by most US states and is intended "to provide a comprehensive and medically sound basis for determining death in all situations".[1] Brain death is a different condition than persistent vegetative state. If the doctors believe there is little to no chance of recovery, then family and loved ones may seek a court order to remove the patient from life support (which is not necessary if the patient or someone with power of attorney has signed a "do not resuscitate," or DNR, order). In the absence of a court order or a DNR, the hospital is obligated to keep the patient alive through artificial means until further notice. Someone who's medically declared brain dead -- meaning there is zero brain activity -- is legally considered dead. A patient considered "highly unlikely" to live beyond a vegetative state, after having gone through rigorous testing, may be diagnosed as being in a persistent vegetative state.
https://healthcare.findlaw.com/patient-rights/brain-death-vs-persistent-vegetative-state-what-is-the-legal-difference.html. Accessed 4/24/2021."

During a review of the hospital's policy and procedure (P&P) titled, "Palliative Medicine Service" (PC 258), dated 6/14/19, the P&P indicated, "Palliative Medicine program is dedicated to providing person-centered compassionate, high values care to patients with serious , life-limiting illnesses. . .assist with goals of care, clarification and Advance Care Planning to ensure alignment between care plan and patient/family goals. . .Referrals: Attending physician completes order in Computerized Physician Order Entry (CPOE) for Palliative Consultation. (Additional orders are managed by Palliative Medicine Service include: Hospice referral and Comfort Care orders). . .Appropriate

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[Palliative] team member contacts patient/family to schedule and conduct an initial assessment and /or family meeting".

During a review of the hospital's policy and procedure (PP) titled, "End of Life Option Act", (PC 245), dated 5/5/17, the P&P indicated, "Use of the End of Life Option for currently hospitalized patients [Facility] and medical staff will consider referral for Palliative Consultation to assist in goals of care clarification and assessment of current pain and symptom management. . . [Facility] may not knowingly participate in or facilitate physician -assisted death and may not provide, deliver, administer, or assist with the administration of any medication intended for physician-assisted death, or be present."

During a review of the hospital's policy and procedure (P&P) titled, "Occurrence Reporting Process", (AP 10), dated 8/26/19, the P&P indicated, " California Code of Regulation, Title CCR, Division 17. 1711 was referred for describing the "Occurrence Reporting process that supports [Facility] Performance Improvement, Patient Safety, Risk Management and Compliance activities. . .Occurrences which may result in actual or potential harm to patients, staff members, or [Facility] visitors. . ." The policy defined Occurrence as an "unusual or unexpected event; adverse drug event as a "variant related to the use of omission of a drug as well as 'close calls' or 'safe catches'"; Statement of Concern as "an event related to an unresolved interpersonal (behavioral) issue. The "Occurrence Repotting process also encompasses unresolved behavioral "Statement of Concern" reporting, compliant and grievance reporting and ADE [adverse drug event] reporting

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"When an incident or unusual event occurs the individual most familiar with the situation. . .shall complete the Occurrence Reporting form. The form will be submitted to the RM (Risk Management) within 5 days of the event, or at the time in which the event is discovered. . .Staff will telephone the RM Department of any unusual event, which results in patient injury immediately".

During a review of the hospital's policy and procedure (P&P) titled, "Sentinel Event and Adverse Event Response and Reporting", (AP 87), dated 8/26/19, the P&P indicated, "For the purposes of this policy, Sentinel Events and Adverse Events shall be considered as one". The policy indicated "adverse events are "the list of CDPH reportable adverse events is defined by California Health and Safety Code Section 1279.1. . .encompass 'Sentinel Events' . . . as well as National Quality Forum's 'never events'" Sentinel events are "a Patient Safety Event" that reaches and results in any of the following: Death, Permanent harm; sever temporary harm and intervention required to sustain life". The policy indicated the process for Sentinel/Adverse events and near misses follows an algorithm: "When an event the is potentially a Sentinel/Adverse or near miss occurs or discovered staff will immediately notify RM Director. . .Risk Management Department will immediately perform an initial assessment . . .concerns of the CRC. . .will occur within 72 hours. . .If upon determination that an Sentinel/Adverse event has occurred, the RM Director shall conduct a RCA. . .the purposes of this section 'adverse events', includes. . .case management events. . .criminal events . . .death or significant injury of a patient or staff member. . ..adverse event or series of adverse events that

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| A 132 | Continued From page 146<br>cause the death or serious disability of a patient, personnel, or visitor." | A 132 | | |
| A 338 | MEDICAL STAFF<br>CFR(s): 482.22<br><br>The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.<br>This CONDITION is not met as evidenced by:<br>Based on observation, interview, and record review, the Medical Staff failed to ensure the medical staff functions reflect the rules, regulations, and its by-laws in the provision of quality medical care to 311 hospital patients, including eligibility and selection of all practitioners, oversight and supervision, as well as the overall accountability to the Governing Body as evidenced by:<br><br>1. The Medical staff/ Medical Executive Committee failed to enforce controlled substance and dangerous drug policy and procedures for three of three Anesthesia Residents (physicians in training, Resident 5, Resident 6, and Resident 7 ) who were required to give-up their responsibility and accountability in the administration and control of controlled substances and directed to hand the controlled substances to their attending/supervising physician [doctor who supervises physicians in training) without regard for the controlled substance chain of custody (tracks controlled substances from the moment they are acquired to the moment they are administered and wasted). This failure resulted in the Anesthesia Residents acting as potential proxies for the attending | A 338 | | |

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physician (MD 1) to obtain controlled substances, in which five of 73 sampled patients (Patient 4, 73, 69, 65, and 29) had documented larger doses of medications given for short procedures (4-7 minutes). (Refer to A0021).

2. The Medical Staff Office failed to follow hospital policy and procedures and bylaws when assessing the professional conduct and adherence to Medical Staff Bylaws for one of one provider (MD 1). This failure resulted in MD 1 being allowed to continue to practice medicine while impaired and diverting patients' medications for self-use. (Refer to A0340).

3. The Medical Staff failed to ensure three of three emergency department physicians (MD 5, MD 6, MD 7) had physician privileges required to provide safe medical care to patients.
This failure had the potential to put patients' safety and health at risk when physicians providing services did not have the appropriate and vetted privileges to perform the procedures or render the services needed to meet patient care. (Refer to A0341).

4. The Medical Staff failed to adhere to medical staff bylaws/ and or contractual agreements for reappointments and /or continued membership for three of three emergency department physicians who did not meet contractual and medical bylaws requirements. This failure resulted in MD 5, MD 6, and MD 7 providing emergency medical care without the appropriate certifications required for the job. (Refer to A0341).

5. The Medical Staff Office failed to have an accountable and reliable processes for staff and

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| A 338 | Continued From page 148<br>providers to investigate, analyze, and address concerns regarding substance disorder, diversion and/or impairment for one of one Provider (MD 1). This failure allowed the Medical Staff Office, the Director of Medical Staff (DMS) to make decisions without Medical Executive Committee review regarding drug diversion, illegal substance use, substance use disorder. (Refer to A0347).<br><br>6. The Medical Staff failed to ensure a supervising physician provided direct supervision to one Emergency Department Resident (physician in training, Resident 1) who was in the residency program for six months. This failure resulted in an inexperienced resident physician to care for a critically ill patient (Patient 1), which resulted in the delay of intubation (inserting a tube into the windpipe to maintain airway and help one's breathing) and mismanagement of a ventilator (a breathing machine that helps the lungs working) post intubation for the patient. Patient 1 died in the Emergency Department six hours after he was brought in by an ambulance. (Refer to A0356).<br><br>The cumulative effects of these systemic failures had the potential to negatively impact health and safety of all patients seeking emergency care at the facility. | A 338 | | |
| A 340 | MEDICAL STAFF PERIODIC APPRAISALS<br>CFR(s): 482.22(a)(1)<br><br>The medical staff must periodically conduct appraisals of its members.<br><br>This STANDARD is not met as evidenced by:<br>The Medical Staff Office failed to follow hospital policy and procedures and bylaws when | A 340 | | |

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assessing the professional conduct and adherence to Medical Staff Bylaws for one of one provider (MD 1). This failure resulted in MD 1 being allowed to continue to practice medicine while impaired (compromised ability to make the right decision for medical care) and diverting (stealing drugs for personal use or sale) patients' medications for self-use.

Findings:

During the Case Review Committee (CRC) Meeting on 03/24/21 at 7:15 AM, Chief Executive Officer (CEO) stated the contracted staff, "abide by Policy and Procedures, contracts and medical staff requirements" and the Governing Body has "responsibility" of all staff and contracted staff for behavior, medical services and safety. CEO stated the medical staff office "refused" to make it a "disciplinary level issue" and refer MD 1 to licensing agencies, i.e. Medical Board of California for diversion and theft of controlled substances. CEO stated, the Governing Body "did not request Medical Executive Committee (MEC) to investigate." CEO stated MD 1 "admitted" to diversion, and since there was "intervention ...didn't need to suspend [MD 1]" and does not require a report to the Medical Board of California. CEO stated, the "intervention" was MD 1 self-referred to Well-Being Committee (a committee which assists physicians with matters related to prevention of impairment and maintenance of health, with particular attention to substance abuse, addiction, mental illness, or behavior) and took a leave of absence. CEO stated it is a violation of [Facility] polices to commit a crime, falsify records, and steal. CEO also stated MD 1 did not "violate" any of [Facility] policies.

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| A 340 | Continued From page 150<br><br>During the CRC meeting on 3/24/21, at 7 AM, the Impairment Provider Policy and the Reporting Guidelines 805.01 were reviewed. CEO acknowledged, MD 1 "admitted" to diversion and impairment from May 2020 to January 2021. CEO stated since MD 1's "behavior did not pose a risk to patients" and "didn't prevent him from working" and "no danger to patients, thus no formal investigation or disciplinary action by MEC was completed. CEO stated reporting guidelines for "805 [CA Business Professional Code requires Agency to report within 15 days if staff privileges are denied or rejected for medical disciplinary cause or reason]" and the "Impairment Provider Policy" did not apply to MD 1. The "Impaired Provider Policy" indicated, "use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and may endanger the individual, his or her co-workers, patients and public...The Chief of Staff or designee shall promptly conduct or supervise the administration of a Screening Physical Exam of the practitioner. . .[And] ask the suspect practitioner to agree to a drug test or alcohol or other testing..."Any violation of this policy" "shall" require testing". Reporting Guidelines for 805.01 (CA Business Professional Code" indicated examples of ground for reporting to the licensing board such as, "incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or herself, any controlled substances"; however, an investigation and MEC disciplinary action must also occur. CEO stated, MEC did not investigate or move to disciplinary action. Of note, the CEO stated, MEC was made aware of MD 1's MIDAS | A 340 | | |

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| A 340 | Continued From page 151<br>(a system for healthcare workers to report 'near misses' and patient safety concerns) reports and diversion for "first time" at the 3/31/21 MEC meeting.<br><br>During an interview on 3/24/21, at 7:15 AM, with Director of Medical Staff (DMS), DMS stated "Medical staff makes the determination" when MD 1 "returns to practice, no matter what condition." DMS acknowledged the medical staff office closed MD 1's MIDAS reports and deemed no further action was required. DMS, stated once MD 1 was referred to "Well-Being Committee," MD 1's diversion, impairment and substance use disorder became "confidential," and Medical staff Office has no obligation to refer to the Medical Board, investigate or refer to MEC. DMS stated MD 1 is on a "leave of absence" and his privileges are on hold. When MD 1 returns to work, privileges can be turned back on.<br><br>During an interview on 3/31/21, at 11 AM, DMS stated, Medical Staff Bylaws and Facility] polices that directly mentioned "medical staff" or "provider" were applicable to medical staff. DMS stated [Facility] Patient Care (PC) polices and Administration Policies (AP) did not apply to providers. DMS was asked if providers were required to follow Policy and procedures such as, Drugs and Alcohol (HR 200), Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse (AP 110), Drug Free Work Place (HR 200), Pyxis Anesthesia System (PAS)", (RX 7.50.0), Medication Administration (PC 19), Procedural Sedation (Moderate) (PC 240), Dangerous Drugs: Theft/Loss (KDEP 11), Medication: Narcotics (PC 67). DMS stated these policies were not "applicable" to medical staff, and they "do not | A 340 | | |

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have to follow." DMS stated the "core" privileges "determine what a physician can do" and certain Medical Staff (MS) polices, like Reporting Guidelines for 805.01 (CA Business Professional Code, Code of Conduct for Medical Staff & Advanced Practice Providers (MS 47), Impaired Provider Policy" (MS 40), Medical Staff Well-Being Committee" (MS 02).

During an interview on 4/1/21, at 8:10 AM with Chief of Staff (MD 2) MD 2 stated, DMS is "my [MD 2] boss"..."Co-boss" of the medical staff office. MD 2 stated Governing Body "gives DMS the authority as Medical Staff Director" to manage medical staff, she "runs the show", and "DMS handles all of it." MD 2 stated, his responsibility was to refer to [DMS], Governing Body "did not need to know about" MD 1's substance use disorder or diversion.

MD 2 stated he is "torn-up about MD 1," and Well-Being will "protect" MD 1. MD 1 overuse and diversion of controlled substance came to his "attention in July 2020" on "separate occasions" from Providers and resurfaced at the start of January 2021. MD 2 stated he "has known MD 1 for 15 years, knows him socially, been to his each other's houses... never seen him impaired." MD 2 stated he did not ask MD 2 specific questions because he "had a good idea what was going on "with fentanyl (narcotic pain medication) and midazolam (sedation medication)." MD 2 stated he "approached" MD 1 and MD 1 denied any substance use disorder. MD 2 stated he, "believed him ... [We] had a personal relationship." MD 2 stated he explained to "MD 1 [by his first name] we're not going to do this, going to stop." MD 2 stated, "I determined no problem" identified, and was "satisfied." MD 2 did

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not refer the MIDAS reports filed for event dates 7/22/20, 1/8/21 and 1/20/21 to the Peer Review Committee (PRC) or Medical Executive Committee (MEC), and were "closed" by Medical Staff Office. MD 2 acknowledged he did not initiate controlled substance audits, investigation or monitoring on MD 1 in July 2020 or January 2021. MD 2 stated, MD 1 "admitted" to controlled substance theft, diversion, and impairment.

During an interview on 3/24/2021, at 5:25 PM, with the Chief of Department of Anesthesia (MD3), MD 3 stated, MD 1, "protected ...can't talk about it". MD 3 stated after concerns of diversion arose, MD 1 continued to be on the anesthesia schedule starting on January 14, 2021. MD 3 stated, MD 1 was scheduled as "vacation" to "decrease suspicion of absence... not make it obvious... keep up [an] image." MD 3 stated there were not any action regarding PRC review, MEC review, disciplinary action, or investigation of MD 1's diversion and impairment while providing patient care. MD 3 stated, there are "short change artists" when reconciliation and diversion are concerned. MD 3 stated, after MD 1 joined the Well-being committee, it all became "confidential" and any action regarding PRC review, MEC review, disciplinary action, and investigation stopped.

During an interview on 3/31/21 at 4:30 PM, with Director of Pharmacy Services (DPS), DPS stated [Facility]" is protecting" MD 1. MD 1 "confessed to diversion" of controlled substance from May 2020 to January 20, 2021 and impairment, and "fentanyl was his drug of choice." DPS stated, "Didn't trust" that MD 1 only used fentanyl. DPS stated the pharmacy department "did not do a deep dive on other

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anesthesiologists ... took a look ... no discrepancies." DPS stated he did not inquire about other controlled substances or Propofol used and accessed by anesthesiologist." DPS acknowledged that residents who obtained medications on MD 1's behalf were not investigated or audited. DPS acknowledged, the pharmacy department did not block residents who worked with MD 1 from obtaining medications on MD 1's behalf.

During an interview on 3/26/21, at 4:05 PM, with Certified Registered Nurse Anesthetist (CRNA 1), CRNA 1 stated, [Facility] "knew of it," MD 1 "diverting versed and fentanyl for years." CRNA 1 relayed her and other CRNA's concerns of MD 1's behavior, overuse of controlled substances and diversion in the summer of 2020 and again January 2021 to MD 2 and/or MD 4. CRNA 1 stated after the complaints in the summer of 2020, MD 1 continued to work, but mainly with residents (physicians in training) and rarely with CRNAs.

During the MEC meeting on 4/1/21, at 10:06 AM, with Medical Director Quality/ Patient Safety (MD 11), MD 11 stated, he reviews MIDAS reports related to patient safety and physician behavior. MD 11 stated someone has "leaked" information regarding diversion, controlled substance misuse, and impairment. MD 11 acknowledged he was aware of MD 1's MIDAS reports but did not forward them to PRC (peer review committee) or MEC.

During a concurrent interview and review, on 4/1/21 at 10:30 AM, with MD 11, MD 1's MIDAS reports dated 7/22/20, 1/8/21 and 1/11/21 were reviewed. The reports indicated:

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1. On 7/22/20, event date 7/22/20, MD 2 submitted a MIDAS report about concerns of possible substance abuse by MD 1, after receiving a complaint from a CRNA. The report was marked as a "physician issue, Behavior. Near miss safety event. MD 2 "determined that physician does not meet the criterion that would require a screening exam" and "there wasn't an issue." Medical Staff Office marks the event "from a medical staff perspective, may close"... Medical Staff Office did not refer MD 1 to PRC or MEC. There was no RCA (root cause analysis, the process of discovering the underlying cause of the problem in order to identify appropriate solutions). MD 1 privileges were not suspended pending an investigation. MD 11 verified the findings.

2. On 1/11/2021, event date 1/8/21, CRNA 1 submitted a MIDAS report about concerns of MD 1 overusing and diverting controlled substances, and patient safety concerns. The report was marked "not a safety event. No known adverse outcome. MIDAS report is reviewed by Director of Risk Management (DRM) and sends a referral to CDPH. Medical Director Quality/ Patient Safety (MD 11) reviewed. Medical Staff Office marks the event "from a medical staff perspective, may close." Medical Staff Office did not refer MD 1 to PRC or MEC. There was no RCA. MD 1 privileges were not suspended pending an investigation. MD 11 verified the findings.

3. On 1/21/2021, event date 1/20/2021, DPS submits a MIDAS report regarding MD 1's admission to diversion starting in July 2020 to January 20, 2021 and impairment due to substance abuse. The report was marked "not a safety event." MIDAS report was reviewed by

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Director of Risk Management (DRM). A self-referral was sent to CDPH on 2/5/2021. Medical staff office reviewed and marked "from a medical staff perspective, may close." Medical Staff Office did not refer MD 1 to PR (Peer Review) or MEC, and did not notify the pharmacy or GB of concerns about MD 1 diverting controlled substances. There was no planned investigation or RCA. MD 1 privileges were not suspended pending an investigation. MD 11 verified the findings.

During a review of the hospital's policy and procedure (P&P) titled, "Peer Review Process" (MS 8710.PR), dated 2/09/21, the P&P indicated, "The Medical Staff assess each credentialed practitioner's professional performance and behavior as part of its ongoing quality and patient safety, credentialing, privileging and corrective action responsibility, including clinical judgement, and appropriate documentation. The Chair of the Peer Review Committee (PRC) will be a regular member of the Medical Executive Committee (MEC) and members will be appointed by the Chief of Staff ... Cases recommended for medical staff peer review may be generated from, the list is not all inclusive, Occurrence reports, Patient Safety Committees, Quality/Safety Departments, Risk Management Department, Midas Reporting process and so forth. Cases recommended for Peer Review are preliminarily screened by Peer Review (PR) Coordinator and presented to the Medical Director or Chief Medical Officer ... If initial reviewer indicates potential conflict of interest, Peer Review (PR) coordinator will assign case to next reviewer. The Chief of Staff will make the final decision on referral to peer review. The PRC will meet monthly, evaluate cases, and make a preliminary determination which will be

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forwarded to the staff member for reply within 30 days. The PRC assigns a final care determination. Results of the peer review process may range from identified opportunities for enhancing care/documentation to identified opportunities of critical importance for improving care. System level opportunities or individual Practioner issues may be identified".

During a review of the hospital's policy and procedure (P&P) titled, "Impaired Provider Policy" (MS 40), dated 5/31/18, the P&P indicated, "Substance abuse can adversely impact patient care and workplace safety. Use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and advance practice providers (APP, include CRNAs, NPs, PAs) to provide services and may endanger the individual, his or her co-workers, patients and public...Whenever a hospital staff members observes evidence of possible impairment by a member of the medical staff or APP, while on hospital premises, the staff member shall immediately inform his or her supervisor who shall inform the CEO or representative ... The Chief of Staff or designee shall promptly conduct or supervise the administration of a Screening Physical Exam of the practitioner...[and] ask the suspect practitioner to agree to a drug test or alcohol or other testing...Any violation of this policy" "shall" require testing."

During a review of the hospital's policy and procedure (P&P) titled, "Code of Conduct for Medical Staff & Advanced Practice Providers" (MS 47), dated 1/30/19, the P&P indicated, practitioners have a responsibility for the welfare of their patients ... the safeguarding of patient care and safety is paramount, and the Medical

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Staff will enforce this policy with disciplinary measures whenever necessary." Examples of "inappropriate behavior means conduct that is unwarranted and reasonable interpreted to be demeaning or offensive," or "blatant failure to respond to patient care needs or staff requests"

During a review of the hospital policy and procedure (P&P) titled, "Reporting Guidelines for 805.01 (CA Business Professional Code", (MS 33), dated 6/26/18, the P&P indicated before reporting actions under 805 and to the applicable licensing board, certain final decisions or recommendations of the Medical Executive Committee covered by this policy must satisfy four elements 1. Deny, terminate of restrict the clinical privileges of a practitioner; 2. Recommendation by the Medical Executive Committee; 3. Following a formal investigation and 4. MECs that any of the following acts have occurred. For example, incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or herself, any controlled substance; repeated acts of clearly excessive prescribing; or sexual misconduct with one or more patients".

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, the P&P indicated, "To be eligible to apply initial appointment or reappointment to the Medical staff physicians, dentists, oral surgeons, podiatrist, and psychologists must among other requirements, "have never been convicted of, or entered a plea of guilty or no contest , to any felony (CRNA, not active staff members according to bylaws, thus need MD); or

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| A 340 | Continued From page 159<br>any misdemeanor relating to controlled substances, illegal drugs...meet any current eligibility requirements that are applicable to the clinical privileges being sought... applying for privileges in an area that is covered by an exclusive contract, meet the specific requirements set forth in that contract...applicants who are not board certified at the time of application must be actively participating in the examination process leading to board certification ...initial applicants who are not board certified and existing Medical Staff members seeking recertification may request additional time to obtain certification or recertification for one additional time period not to exceed two years".<br><br>The "Medical Staff Bylaws" further indicated the "Factors for Evaluation," which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, and safely, competently perform clinical privileges, and commitment to quality care... Basic Responsibilities and Requirements. "As a condition of being granted appointment or reappointment and a condition of ongoing membership, every member specifically agrees to the following," but not limited to, provide continuous and timely quality of care to all patients for whom the individual has responsibility, effective and efficient hand-offs for safe patient care; to abide by all Bylaws, polices and Rules and Regulations of the Medical Staff; to comply with clinical practice or evidence based protocols and pathways that are established by, and must be reported to, regulatory or accrediting agencies or patient safety organizations...any changes in the practitioner's ability to safely and completely exercise privileges or perform the duties and responsibilities of appointment | A 340 | | |

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because of health issues, including, but not limited to, impairment due to addiction, alcohol use, or other similar issue (all of which shall be referred for review under the Impaired Provider Policy); to immediacy submit to an appropriate evaluation, which may include diagnostic testing (such as blood and/or urine; to refrain from delegating responsibility for hospitalized patients to any individual who is not qualified or adequately supervised; to refrain from deceiving patients as to the identity of any individual providing treatment or services; to seek consultation whenever required or necessary; to complete in a timely and legible manner all medical and other required records, containing all information required by [Facility]; to cooperate with the Chief of Staff, the MEC and the CEO in good faith. The MEC (or subcommittee of its members appointed by the Chief of Staff) will review the quality of care and service implications of the proposed exclusive contract or Board resolution."

The "Medical Staff Bylaws," also indicated "the Chief of Staff shall update the CEO, in the event that the MEC fails to initiate an investigation in response to concerns raised about a Medical Staff member's competence, performance, or professional conduct in accordance with this article and the Board determines that such decisions is contrary to the weight of the evidence, the Board may direct the MEC to initiate such an investigation...The investigation committee" shall have the authority to review relevant documents and interview individual." The investigating committee "may require a physical, mental and/or behavioral examination of the individual by health care professional(s) acceptable to it." The investigating committee

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shall make a reasonable effort to complete the investigation and issue its report within 30 days of the commencement of the investigation ... The MEC may accept, modify, or reject any recommendations it receives from an investigating committee." The MEC "shall consist of the Chief of Staff, Vice Chief of Staff, Chair of Peer Review responsibility: recommending directly to the Board on such items as Medical Staff appointment and reappointment and Medical Staff appointment termination ... Peer Review appointed by Chief of Staff, never as a voting member, "shall review cases in which an individual patient's care has been or may have been compromised by the care provider".

The Medical Bylaws further indicated the "Factors for Evaluation," which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, and safely, competently perform clinical privileges, and commitment to quality care ...Whenever a serious question has been raised regarding: the clinical competence or clinical practice of any member of the Medical Staff, including care, treatment to management of a patient or patients; the safety or proper care being provided to patients; conduct by any staff member considered lower than the standard of [Facility]. The matter may be referred to the Chief of Staff, the chair of the department, the chair of the standing committee, or the CMO. If the board becomes aware of information that raises concern about any Medical Staff member shall be referred the Chief of Staff, the chair of the department, the chair of the standing committee, CMO, or the CEO to the for review and appropriate action. "The person whom the matter is referred shall conduct or arrange an inquiry which shall include the Chief of Staff to

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determine whether the question raised has sufficient credibility to warrant further review and, if so, shall forward it in writing to the MEC." "No action taken pursuant to this Article shall constitute an investigation." "In the event that the MEC fails to initiate an investigation in response to concerns raised about a Medical Staff member's competence, performance, or professional conduct in accordance with this article and the Board determines that such decisions is contrary to the weight of the evidence, the Board may direct the MEC to initiate such an investigation." "The committee conduction the investigation, the investigation committee") shall have the authority to review relevant documents and interview individual." The investigating committee "may require a physical, mental and/or behavioral examination of the individual by health care professional(s) acceptable to it." The investigating committee shall make a reasonable effort to complete the investigation and issue its report within 30 days of the commencement of the investigation." "The MEC may accept, modify, or reject any recommendations it receives from an investigating committee."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, "The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in [Facility]... prompt and accurate completion of portions to the medical record for which he or she is responsible ... performing all other duties described in these Rules and Regulations ...Abuse and losses of controlled substance will be reported in accordance with applicable federal and state

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| A 340 | Continued From page 163<br>laws, to the individual responsible for the pharmaceutical service, to the Chief Executive Officer and others per medical staff policy ... Medication orders will be entered directly into the electronic medical record by the ordering physician ...accurate and complete medication reconciliation ... All verbal orders will include the date, and time of entry into the medical record, identify the names of the individual who gave, received and implemented the order, and then be authenticated with the date and time by the ordering practitioner".<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Dangerous Drugs: Theft/Loss," (KDEP 11), dated 6/19/2019, indicated "outlined the proper procedure in the case of theft/loss of controlled substance, chemicals listed in the Department of Justice Manual (List 1 Chemicals, substances regulated pursuant to Section 11100 of the Health and Safety Code) or significant quantities of other dangerous drugs ...Federal law required action to be taken by sites licensed by the Drug Enforcement (DEA) should a loss of controlled substances in List 1 chemicals occur by any of the following mean: break-in, employee theft ...loss in transit ...Per Administrative Policy (AP 110), the following agencies will be notified: 1. DEA Diversion Field Office by completing DEA form 106 "Report of Loss or Theft of Controlled Substance "within one business day of the discovery of a theft or significant loss of a controlled substance. 2. Department of Justice within 3 business days of the discovery of a theft or loss of any substance regulated pursuant to Health & Safety Code Section 11100. 3. State Board of Pharmacy within 30 days from the discovery of any loss of controlled substances or | A 340 | | |

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within 14 calendar days from the date of loss for losses due to licensed employee theft (pursuant to Business and Professional Code 4104). 4. Profession licensing or certifying board of the person confirmed to have diverted drugs. 5. [Local] Police and /or other law enforcement agency. 6. California Department of Public Health.

Review of policy and procedure (P&P) titled, "Personnel management: Public Protection & Reporting Requirements," (KDEP 15), dated 11/10/14, the P & P indicated "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or her license will be addressed promptly." The P & P "outlined procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it effects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs ... in the interest of protecting the public, follows established procedures: Human Resource Policy HR 200, 'Drugs and Alcohol"; Administrative Policy AP 110, "Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse," and Reporting to the California Board of Pharmacy within 14 days of receipt or development of the following information with regards to any licensed individual employed by or with the pharmacy": theft, diversion, or self-use of dangerous drugs, physical or mental impairment.

During a review of the hospital's policy and

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procedure (P&P) titled, "Drug Free Work Place and Drug/Alcohol testing," (HR 200), dated 4/29/19, the P&P indicated, "The "[Facility] has established this policy on the use or abuse of alcohol and illegal drugs or other controlled substances by employees, contract staff or volunteers. At work or otherwise, substance abuse seriously endangers the safety of the work environment, as well as our patients and the general public ... [Facility] has established this policy to detect users and remove abusers of drugs and alcohol and to prevent the use and/or presence of these substances on the workplace. Confirmed incidents of drug diversion will be reported to the appropriate agencies...[Facility] may suspend employees without pay under this policy pending the results of a drug test or investigation...'Illegal drugs or other controlled substances' means any drug or substanc3e that is not legally obtainable; or is legally obtainable but has not been legally obtained; or has been legally obtained but is being sold or distributed unlawfully ... 'Abuse of any legal drug' means the use of any legal drug: for any purpose other than the purpose for which it was prescribes or manufactured ...'Reasonable suspicion includes suspicion that is based on specific personal observations ... information provided to management by an employee, by law enforcement officials, or by other persons believed to be reliable; or suspicion based on other surrounding circumstance ...'Drug diversion' means that an employee has the substance on his or her person or otherwise under his or her control ...Drug Use Prohibitions: violation of following will result in reporting the employee to a licensing board or agency, law enforcement agencies and /or /disciplinary action , up to and including termination of employment. The

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Director of Pharmacy or designee will determine the necessity of reporting to Drug Enforcement Agencies, the California Board of Pharmacy and Police. Human resources will report employee's licensing or certifying board as necessary. The Risk Management department will report to the California Department of Public Health as appropriate. 1. The unlawful use, sale, purchase, possession, manufacture, distribution, or dispensation of any drug or prescribed controlled substance on property or during work time is against policy ...Testing of Current Employees: Employees must submit to a drug test if reasonable suspicion exists ...Reasonable suspicion testing means drug testing based on a belief that an employee is using or has used drugs in violation of [Facility] policy. Among other things, such facts and inferences may be based upon: Direct observations ...abnormal conduct ...a report of drug use, provided by a reliable and credible source ...evidence that an employee has used, possessed, sold, solicited or transferred drugs while working or on[Facility] premises or while operating [Facility] vehicles, machinery or equipment ...Audit findings or charting issues ...Actions to be taken by Management: There may be instance where supervisors /managers have reasonable cause to believe that employee consumed drugs on [Facility] premises or reported to work under the influence of one or both. In these instances management may request a drug test ....If the employee refuse to sign the consent [for drug testing] or provide a sample, he/she will be subject to Disciplinary action up to and including termination of employment ....Drug-Free contract and follow-up testing: As a condition of employment and /or continued employment, participants in a rehabilitation program for drug and/or alcohol

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| A 340 | Continued From page 167<br>abuse must consent in writing via a [Facility] Drug-Free Contract to periodic unannounced testing for a period up to two (2) years after returning to work."<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug Diversion Illegal Substance Abuse or Controlled Substance Abuse," (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion." | A 340 | | |
| A 341 | MEDICAL STAFF CREDENTIALING<br>CFR(s): 482.22(a)(2) | A 341 | | |

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| A 341 | Continued From page 168<br>The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Medical Staff failed to :<br><br>1. Ensure three of three emergency department physicians (MD 5, MD 6, MD 7) had physician privileges required to provide safe medical care to 311 hospital patients. This failure had the potential to put patients' safety and health at risk when physicians providing services did not have the appropriate and vetted privileges to perform the procedures or render the services needed to meet patient care.<br><br>2. Adhere to medical staff bylaws and or contractual agreements for reappointments and or continued membership for three of three Emergency Department Physicians (MD 5, MD 6, and MD 7) who did not meet contractual and medical bylaws requirements. This failure resulted in MD 5, MD 6, and MD 7 providing emergency medical care without the appropriate certifications required for the job and resulted in medical staff members not meeting hospital standards for medical staff membership.<br><br>Findings: | A 341 | | |

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1. During an interview on 3/29/21, at 4:05 PM, with Graduate Medical Education Program Director, Anesthesia (MD 4), MD 4 stated, physicians need to be "qualified" to administer Propofol (sedation medication that is divertible and fatal when used inappropriately). MD 4 stated, Propofol was "signed off to secure airways" by the Medical Executive Committee (MEC). MD 4 stated, "Propofol IV [intravenous] [has] planes of anesthesia ...moderate [sedation]-- able to respond to verbal stimuli [voice] ...deep [sedation]-move to noxious [pain] ...general [anesthesia]-need to control ventilation, [patient] will not respond to noxious stimuli ..." and physicians need privileges for moderate, deep and general anesthesia. MD 4 stated per ASA (American Society of Anesthesia) guidelines, practitioners must be "qualified to give anesthesia." MD 4 stated according to Medical Staff Rules and Regulations, "Anesthesia means general or regional anesthesia, monitored anesthesia care or deep sedation." Procedural Sedation (Moderate) policy and procedure, "anesthesia involves the administration of medications to produce a blunting or loss of pain perception (analgesia; voluntary and involuntary movement; autonomic function [automatic]; and memory and/or consciousness."

During a concurrent interview and record review, on 3/23/21, at 3:35 PM, with Emergency Department Physician (MD 5), the hospital's Medical Staff Emergency Medicine and Anesthesia Privileges Forms were reviewed. MD 5 verified he does not have privileges for deep sedation or anesthesia. MD 5 stated ED physicians have privileges and provide services for procedures, which include intubation and

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moderate sedation with Propofol management of intubated patients, airway management, cardio pulmonary resuscitation (CPR, life saving measures of breathing and chest compressions). MD 5 acknowledged prescribing orders for Propofol infusion and pain medications to maintain unresponsiveness while a patient is intubated (breathing tube in windpipe). According to Medical Staff Rules and Regulations, "Anesthesia means general or regional anesthesia, monitored anesthesia care or deep sedation." Procedural Sedation (Moderate) policy and procedure, defined "anesthesia involves the administration of medications to produce a blunting or loss of pain perception (analgesia; voluntary and involuntary movement; autonomic function [automatic]; and memory and/or consciousness." Privileges for Propofol infusions and deep general anesthesia are not listed on the Emergency Department privilege form. MD 5 acknowledged he was not approved for deep sedation. MD 5 stated this should be on the privilege form and "it's a problem" they are not. Propofol infusions, and deep general anesthesia are not listed on the emergency department privilege form. MD 5 stated, he does not have privileges for deep sedation or anesthesia, palliative care, neurology, deterring brain death, critical care."

During a concurrent interview and record review on 3/24/21 at 2:35 PM, with Emergency Department Physician (MD 6), the hospital's Emergency Medicine and Anesthesia Privilege Forms were reviewed. MD 6 verified he did not have Anesthesia privileges. MD 6 stated, ED clinical privileges are like "critical care, intubation, CPR, airway management." MD 6 stated, medical staff privileges provide services for

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sedation and to use Propofol as needed. MD 6 acknowledged prescribing orders for Propofol infusion and he gives pain medications to maintain unresponsiveness while a patient is intubated (breathing tube in windpipe). MD 6 acknowledged he was not approved for anesthesia privileges. According to Medical Staff Rules and Regulations, "Anesthesia means general or regional anesthesia, monitored anesthesia care or deep sedation." Procedural Sedation (Moderate) policy and procedure, defined "anesthesia involves the administration of medications to produce a blunting or loss of pain perception (analgesia; voluntary and involuntary movement; autonomic function [automatic]; and memory and/or consciousness." MD 6 reviewed the ED privileges list for MD 6 and stated he does not have privileges for intubation, Propofol, CPR, airway management. MD 6 acknowledged ED privileges do not include palliative care, anesthesia, hospice, neurology. Propofol infusions and deep and general anesthesia are not listed on the emergency department privilege form.

During a concurrent interview and record review on 3/29/21, at 7:05 PM, with Emergency Department Physician (MD 7), the hospital's Emergency Medicine and Anesthesia Privilege Forms were reviewed. MD 7 acknowledged he was not approved for anesthesia privileges. MD 7 stated he has ED privileges and provides services for procedures, moderate sedation, airway management, Cardiopulmonary (CPR) resuscitations, and ultrasound. MD 7 acknowledges he uses anesthesia medications (Etomidate, Propofol, Rocuronium), medications that induce unconsciousness and unresponsiveness to pain. MD 7 acknowledged,

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he orders Propofol infusion and gives pain medications to maintain unresponsiveness while a patient is intubated (breathing tube in windpipe). According to Medical Staff Rules and Regulations, "Anesthesia means general or regional anesthesia, monitored anesthesia care or deep sedation." Procedural Sedation (Moderate) policy and procedure, defined "anesthesia involves the administration of medications to produce a blunting or loss of pain perception (analgesia; voluntary and involuntary movement; autonomic function [automatic]; and memory and/or consciousness". MD 7 verified privileges for Propofol infusions and deep and general anesthesia are not listed on the Emergency Department privilege form. Except for ultrasound and moderate sedation, MD 7 could not locate all of the medical services he provides on the Emergency Medicine privilege on the form. MD 7 stated "will follow-up and talk with medical staff."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, the P&P indicated "'supervising physician' as a member of Medical Staff with clinical privileges who has agreed in writing to supervise or collaborate with an Advanced Practice Provider and to accept full responsibility for the actions of the Advanced Practice Provider ..." Defined "'Special Privileges' means privileges that fall outside the core privileges for a given specialty that require additional education, training, and/or experience beyond that is required for core privileges in order to demonstrate competence." To be eligible to apply for initial appointment or reappointment to the Medical staff physicians, dentists, oral surgeons, podiatrist, and psychologists must among other

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requirements, "have never been convicted of, or entered a plea of guilty or no contest, to any felony (CRNA, not active staff members according to bylaws, thus need MD); or any misdemeanor relating to controlled substances, illegal drugs...meet any current eligibility requirements that are applicable to the clinical privileges being sought ...if applying for privileges in an area that is covered by an exclusive contract, meet the specific requirements set forth in that contract...applicants who are not board certified at the time of application must be actively participating in the examination process leading to board certification...initial applicants who are not board certified and existing Medical Staff members seeking recertification may request additional time to obtain certification or recertification for one additional time period not to exceed two years".

During a review of the physician contract agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department," dated 8/20/20, the P&P indicated "Physicians shall be Board certified in Emergency Medicine or eligible to and actively pursuing Board Certification in emergency medicine..." "All physicians must have successfully completed the American College of Surgeons Advanced Trauma Life Support (ATLS) course, and all non-Board Physicians shall maintain current ATLS status...Medical Group shall require all Medical Group Personnel to: provide services under this Agreement in accordance with appropriate standards of clinical practice, all applicable federal and state laws and regulations, all applicable rules in regulations of the Medical Board of California, and the Standards of the American Board of Emergency

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Medicine...Comply with all applicable medical staff bylaws, rules, regulations, policies and procedures of the[Facility], including code of conduct and conflict of interest policies and procedures...Comply with all applicable standards.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, the P&P indicated "Factors for Evaluation," which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, safely, and competently perform clinical privileges, and commitment to quality care ... continuous and timely quality of care to all patients for whom the individual has responsibility... "

During a review of the hospital's policy and procedure (P&P) titled, "Surgery/Procedures at the Bedside: Guidelines and Documentation Recommendations for Urgent/Emergency Situations," (AP 229), dated 5/24/16, the P&P indicated, "Critical care attending, anesthesiologist, or proceduralist with current clinical privileges to perform the desired procedure will oversee the medical management of the patient during the procedure, This will include sedation, analgesia, airway management or ventilator management, and hemodynamic monitoring if applicable..." informed consent will be obtained by the physician preforming the procedure ...Informed consent is waived in the event of emergency..."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, indicated, "if applying for privileges in an area that is covered by an

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exclusive contract, meet the specific requirements set forth in that contract...applicants who are not board certified at the time of application must be actively participating in the examination process leading to board certification.
The Medical Bylaws further indicate the "Factors for Evaluation", which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, and safely, competently preform clinical privileges, and commitment to quality care ... 'Special Privileges' means privileges that fall outside the core privileges for a given specialty that require additional education, training, and/or experience beyond that is required for core privileges in order to demonstrate competence"

During a review of the hospital's policy and procedure (P&P) titled, "Procedural Sedation (Moderate): Adults and Pediatric Patient," (PC 240), dated 10/22/20, the P&P indicated moderate procedural sedation is only to be performed by faculty anesthesiologist or Qualified physicians and assisted by a Qualified Registered Nurse (RN) and applies to adults in the Emergency Department. Moderate sedation/analgesia was defined as "a drug induced depression of consciousness during which patients respond purposeful to verbal commands, wither alone or accompanied by light tactile [touch] stimulation". Deep sedation was defined as: a drug induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimuli [touch] ... Patients may require assistance in maintaining ventilatory function [breathing] may be impaired ... If deep sedation is required, the Department of

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Anesthesiology should be consulted".

During a review of the hospital's policy and procedure (P&P) titled, "Procedures Not Permitted in the Emergency Department," (ED 1001), dated 5/17/18, the P&P indicated general anesthesia "will not be permitted in the emergency department (ED) at any time".

2. During a concurrent interview and credential file review, on 3/31/21, at 11 AM, with Director of Medical Staff (DMS), three emergency department physicians (MD 5, MD 6, and MD 7) credential files were reviewed. The emergency department physicians did not meet contractual requirements as follows:

a) MD 5, MD 6, and MD 7 did not have the required Advance Trauma Life Support (ATLS - a training program for medical providers in the management of acute trauma cases, and provide the physicians with a safe and reliable method for immediate management of injured patients) Certifications.

b) MD 7 did not have the required Advanced Cardiac Life Support (ACLS-refers to a set of clinical algorithms for the urgent treatment of cardiac arrest, stroke, myocardial infarction (also known as a heart attack), and other life-threatening cardiovascular emergencies) Certification

c) MD 7 did not have the required board certification for Emergency Medicine.

d) MD 5 was approved without assessment to demonstrate competence for moderate sedation.

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e) MD 5, MD 6, MD 7, and MD 14 did not have privileges for Propofol for deep sedation or Propofol infusions.

DMS stated, "Emergency room physician core privileges do not include anesthesia privileges for example, deep and general anesthesia."

f) MD 5, MD 6, MD 7, and MD 14 did not agree in writing to supervise residents.

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, "The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in the [Facility]"

During a review of the hospital's policy and procedure (P&P) titled, "Performance Management and Competency Assessment Program" (HR 213), dated 12/19/19, the P&P indicated, "Competency is the demonstrated ability to integrate the knowledge, skills, and attitude required in a designated role or setting...All employees must successfully complete all required training by the due dates established...Documentation of completion is recorded in the HR system and written documentation may be maintained in Human Resources or department employee's file."

During a review of the physician contract agreement titled, "[Facility] Amended and Restates Professional Services Agreement Emergency Department," dated 8/20/2020, the physician contract agreement indicated, "Physicians shall be Board certified in Emergency

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| A 341 | Continued From page 178<br>Medicine or eligible to and actively pursuing Board Certification in emergency medicine... All physicians must have successfully completed the American College of Surgeons Advanced Trauma Life Support (ATLS) course, and all non-Board Physicians shall maintain current ATLS status...Medical Group shall and shall require all Medical Group Personnel to : provide services under this Agreement in accordance with appropriate standards of clinical practice, all applicable federal and state laws and regulations, all applicable rules in regulations of the Medical Board of California, and the Standards of the American Board of Emergency Medicine...Comply with all applicable medical staff bylaws, rules, regulations, policies and procedures of the[Facility], including code of conduct and conflict of interest policies and procedures...Comply with all applicable standards."<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws," dated 12/21/20, the P & P indicated, 'supervising physician' as a member of Medical Staff with clinical privileges who has agreed in writing to supervise or collaborate with an Advanced Practice Provider and to accept full responsibility for the actions of the Advanced Practice Provider ..." Defined "'Special Privileges' means privileges that fall outside the core privileges for a given specialty that require additional education, training, and/or experience beyond that is required for core privileges in order to demonstrate competence". To be eligible to apply initial appointment or reappointment to the Medical staff physicians, dentists, oral surgeons, podiatrist, and psychologists must among other requirements, "have never been convicted of, or | A 341 | | |

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| A 341 | Continued From page 179<br>entered a plea of guilty or no contest , to any felony (CRNA, not active staff members according to bylaws, thus need MD); or any misdemeanor relating to controlled substances, illegal drugs...meet any current eligibility requirements that are applicable to the clinical privileges being sought...if applying for privileges in an area that is covered by an exclusive contract, meet the specific requirements set forth in that contract... applicants who are not board certified at the time of application must be actively participating in the examination process leading to board certification...initial applicants who are not board certified and existing Medical Staff members seeking recertification may request additional time to obtain certification or recertification for one additional time period not to exceed two years..." | A 341 | | |
| A 347 | MEDICAL STAFF ORGANIZATION & ACCOUNTABILITY<br>CFR(s): 482.22(b)(1), (2), (3)<br><br>The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.<br><br>(1) The medical staff must be organized in a manner approved by the governing body.<br><br>(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.<br><br>(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:<br>(i) An individual doctor of medicine or | A 347 | | |

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osteopathy.
(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.
(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

This STANDARD is not met as evidenced by:
Based on interview and record review, the Medical Staff Office failed to have an accountable and reliable processes for staff and providers to investigate, analyze, and address concerns regarding substance disorder, diversion and/or impairment for one provider (MD 1). This failure caused the Medical Staff Office and the Director of Medical Staff (DMS) to make decisions without Medical Executive Committee's review regarding drug diversion, illegal substance use, substance use disorder.

Findings:

During an interview on 03/24/2021, at 7:15 AM, with the Chief Executive Officer (CEO) on Case Review Committee (CRC, a group of physicians and the hospital's chief nursing office to evaluate unusual incidents) Meetings. The CEO stated the contracted staff, "abide by policy and procedures, contracts, and medical staff requirements. The Governing Body has "responsibility" to oversee all staff including contracted staff's behavior, medical services provided, and patient safety. The CEO stated, the medical staff office "refused" to make it a "disciplinary level issue" and did not refer the Chief of Department of Anesthesia (MD 1) to the Medical Board. The CEO stated, the Governing Body, after being informed of MD 1 using illegal

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substance, "did not request the Medical Executive Committee (MEC, a team of physicians that monitor and review physician behavior, conduct and patient safety) to investigate." The CEO stated, MD 1 was given a choice to take a drug test or go to Well-Being Committee (a committee which assists physicians with matters related to prevention of impairment and maintenance of health, with particular attention to substance abuse or addiction, mental illness, or behavior). The CEO stated, MD 1 "self-reported to Well-Being Committee, enrolled in inpatient rehabilitation, and took a voluntary leave of absence." The CEO stated, MD 1 did not "need to do a drug test" or "be suspended." The CEO stated, since there was "intervention ...don't need to suspend [MD 1]." The CEO stated, once a staff is enrolled in "Well-Being Committee," there was no need to take any further actions. The CEO stated, using illegal substance was a violation of [Facility] polices to commit a crime, falsify records and steal. The CEO stated, MD 1 did not "violate" any of [Facility] policies.

During an interview on 3/31/21, at 11 AM, with the Director of Medical Staff (DMS), the DMS stated, "medical staff makes the determination" when MD 1 "returns to practice, no matter what condition." DMS stated she was acting on "behalf of the MEC." The DMS stated, if medical staff office is not "satisfied" with physician's progress, medical staff office will refer the provider to "MEC." The DMS stated, the medical staff office closed MD 1's drug diversion report and no further action required. The DMS stated, once MD 1 was referred to "Well-Being Committee", MD 1's diversion, substance use disorder becomes "confidential" and Medical staff has no obligation to refer to the Medical Board. The

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report was not referred to MEC or Peer Review Committee (PRC, a committee that is responsible for investigating patient, member or practitioner complaints or concerns about the quality of clinical care or service provided and to make recommendations for corrective actions, if appropriate).

During an interview on 4/2/21, at 8:20 AM, with the Chief of Staff (MD 2), MD 2 stated, DMS is the "my [MD 2] boss" and "Co-boss" of the medical staff office. MD 2 stated, the Governing Body "gives DMS the authority as medical staff director to manage medical staff" and "runs the show," and DMS "handles all of it." MD 2 stated, his responsibility was to refer to Director of Medical Staff (DMS), the Governing Body "did not need to know about" MD 1's substance use disorder or diversion." MD 2 stated, if medical staff office is "not satisfied" with MD 1's progress, DMS would refer MD 1's controlled substance, diversion and staff behavior to MEC. MD 2 stated he did not initiate controlled substance audits, investigation, or monitoring of MD 1 in July 2020 or January 2021. MD 2 stated, MD 1 "admitted" to controlled substance theft, diversion, and impairment. MD 2 stated, after MD 1 took a "leave of absence" and enrolled in the Well-Being Committee, reporting to the Medical Board would not be required. MD 2 stated, there were "no adverse events," safety concerns, or patient harm from MD 1's drug diversion, a referral to PRC or MEC was not necessary. MD 2 stated, he determined "no problem" identified and the outcome was "satisfied."

During an interview on 3/31/21, at 4:20 PM, with Director of Pharmacy Services (DPS), DPS stated, on 1/20 /2021, he was "summoned" to

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DMS's medical staff office. DMS and MD 1 were at the meeting when MD 1 "confessed to diversion" of controlled substance and impairment from 5/20 to 1/20/21. DPS stated, the Medical Staff Office was aware of the diversion because, "I was summoned by DMS." DPS stated, it would be medical staff's decision to refer MD 1 to PRC and MEC.

During an interview on 3/29/21, 4:05 PM, with Graduate Medical Education Program Director Anesthesia/Vice Chief, Department of Anesthesia (MD 4), MD 4 stated, he and MD 2 had a meeting with MD 1 to discuss controlled substance diversion and misuse complaints. MD 4 stated, "Drug testing was suggested" to MD 1, but MD 1 refused. MD 4 and MD 1 discussed Well-Being Committee, and MD 1 self-referred to Well-Being Committee. MD 4 stated, MD 1's drug diversion became "confidential" once the provider enters the Well-Being Committee. MD 2 did not refer MD 1 to Peer Review or MEC of concerns about MD 1 diverting controlled substances and impairment.

During a review of the MEC meeting minutes with Medical Director Quality/Patient Safety (MD 11), Chief of Department of Anesthesia (MD 3), Vice Chief of Department of Anesthesia (MD 4), MD Critical Care (MD 8), and the following events were reported to MEC:

a) On 7/22/20, event date 7/22/20, MD 2 submitted a report about concerns of possible substance abuse by MD 1, after receiving a complaint from a CRNA. The report was marked as a "physician issue, Behavior. Near miss safety event." The report indicated, MD 2 "determined that the physician (MD 1) does not meet the criterion that would require a (drug) screening

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exam" and "there wasn't an issue." Medical Staff Office marked the event "from a medical staff perspective, may close." Medical Staff Office did not refer MD 1 for Peer Review or to MEC. There was no further investigation to identify appropriate solutions. The Medical Staff Office did not suspend MD 1's privileges.

b) On 1/11/21, event date 1/8/21, a Certified Registered Nurse Anesthetist (CRNA 1) submits a report about MD 1 overusing and diverting controlled substances. CRNA 1 had concerns on patient safety. The report was marked as "not a safety event. No know adverse outcome." The report was reviewed by the Director of Risk Management (DRM) and the Medical Director Quality/ Patient Safety (MD 11). Medical Staff Office marked the event "from a medical staff perspective, may close." Medical Staff Office closed the event and did not refer MD 1 to Peer Review or MEC. There was no further investigation to identify appropriate solutions. The Medical Staff Office did not suspend MD 1's privileges.

c) On 1/21/2021, event date 1/20/2021, DPS submits a report regarding MD 1's admission to diversion, from July 2020 to Jan 20, 2021, and impairment due to substance abuse. The report was marked as a "not a safety event." The report was reviewed by the Director of Risk Management (DRM). The Medical Staff Office reviewed the report and marked, "from a medical staff perspective, may close." The Medical Staff Office did not refer MD 1 to Peer Review or MEC. The Medical Staff Office did not notify the pharmacy or GB of DPS's concern about MD 1 diverting controlled substances. There was no further investigation to identify appropriate

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solutions. The Medical Staff Office did not suspend MD 1's privileges.

During an interview on 4/1/21, at 11 AM, with the MEC, a Critical Care Physician (MD 8) stated, he was the most senior physician on the MEC. MD 8 stated the MEC responsibilities are to review and monitor patient safety concerns and physician behavior, and determine disciplinary actions. MD 8 stated, the MEC shares findings with the Governing Board. MD 8 stated, provider behavior and patient care concerns need to be entered in an electronic occurrence reporting system to reach Peer Review Committee or for MEC review. MD 8 stated, substance use disorder and diversion should have "high" priority for review by MEC and [Facility]. MD 8 stated, when reconciliation and diversion are concerned, "quality data is collected on physician investigations and adverse actions, and drug shortages. MD 8 stated, MEC was notified of MD 1's drug diversion last night (3/31/21). MD 8 stated, he was not aware of the reports for event dated 7/22/21, 2/8/20, and 12/20/20 until last night, 3/31/21. MD 8 stated, the reports were first reviewed by MD 11 and Medical Staff Office. MD 8 stated, MD 1 should have "done a urine toxicology (urine drug screen), and reported to the Medical Board." MD 8 stated, Director of Medical Staff Office (DMS) has "no authority" over the medical staff" and (DMS) does not supervise physicians." MD 8 stated, DMS is a "secretary." DMS "coordinates meetings and arranges rooms and takes notes at meetings."

During an interview on 4/1/21, at 11:15 AM, with the MEC, MD 11 stated, he was aware of MD 1's occurrence report for the event dated 1/8/21. MD 11 stated, he did not forward it to MEC because

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"someone has leaked" information regarding MD 1's diversion, drug paraphernalia, controlled substance disuse, and impairment. MD 11 stated, MD 1 was not referred to MEC or Peer Review because he went on a leave of absence. MD 11 stated, MD 1 was "not a risk to patient safety."

During an interview on 4/1/21, at 11:45 AM, with the Chief of Department of Anesthesia (MD 3), MD 3 stated, DMS did not supervise physicians and was not a member of MEC. MD 3 stated, DMS was a secretary, did paperwork and ran the medical staff office. MD 3 stated, if physician concerns and patient safety issues were not reported using the electronic report system, the concerns would "not be known" to MEC or PRC, and there would be "no monitoring ...no trends." MD 3 stated, the Medical Staff Office needed to use the electronic reporting system to refer providers to Peer Review Committee or MEC for review and possible action.

During a concurrent interview and record review on 3/30/21, at 9:30 AM, with Risk Management Specialist (RMS 1), RMS 1 reviewed the reports and stated, if there were "any problems" with a provider, the incident should be reported via an electronic occurrence reporting system to address medications, patient safety, or behavior concerns. RMS 1 stated, the reports would be reviewed by Risk (Risk Department) and forwarded to Medical Staff Office. RMS 1 stated, the Chief of Medical Staff (MD 2) and the Medical Staff Office were "responsible" for the review of the reports and refer adverse events, behavior affecting patient safety, or patient safety concerns to Peer Review Committee or MEC. RMS 1 stated, had the report referred to Peer Review Committee, the Committee would review and

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determine if disciplinary action was required. Once Peer Review Committee determined disciplinary action was required, the provider would be referred to the MEC. RMS 1 stated, if the report was not referred to Peer Review or MEC, the report "would not reach RCA (the process of discovering the root causes of problems) level," and "won't appear on adverse drug committee or Risk Management Committee." RMS 1 stated, MD 1 was not reported to PRC or MEC, and thus would not reach root cause analysis.

During a review of the hospital's policy and procedure (P&P) titled, "District Bylaws" for [Facility name], dated 4/27/20, the P&P indicated, "The[Facility name] mission and vision are to "support the safety and quality of care, treatment and service[and] committed to ethical and legal business practices, integrity, accountability and excellence ...Quality oversight responsibilities, the Board must ...Understand and accept responsibility for the actions of all physicians nurses and other individuals who perform their duties in the organization's facilities ...Carefully review recommendations of the Medical Staff...Fully understand the Board's responsibilities ad relationships with the Medical Staff and maintain effective mechanisms for communication with them ...Monitor programs and services to ensure they comply with policies and standards ...take corrective action when appropriate ...understand and communicate the roles and function of the Board, committees, Medical Staff and management ...Enforce Board and hospital bylaws rules and regulations. . .The Chief Executive Officer (CEO) 'shall act on behalf of the Governing Body in the overall management of the [Facility]'...THE CEO shall

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select, employ and have authority to discharge any employee of the [Facility name] other than any individual with the title or equivalent function ...The CEO shall keep abreast and be informed of new developments in the medical and administration areas of the hospital administration ...The [Facility name] 'organized medical staff is accountable to the Governing Body , the term "medical staff" also refers, for example, to the physicians who are members of a Medical Group, an IPA, a medical specialty society, or a component society of the CMA that maintains a Well-Being Committee for the benefit of its members. In any context, the Well-Being Committee serves as one of an array of mechanisms physicians should utilize to assure patient safety. A general summary of its actions should be reported to the Medical Executive Committee and/or other organizational governing body at least quarterly."

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Guidelines for 805.01 (CA Business Professional Code", (MS 33), dated 6/26/18, the P&P indicated, before reporting actions under 805 and to the applicable licensing board, certain final decisions or recommendations of the Medical Executive Committee covered by this policy must satisfy four elements 1. Deny, terminate of restrict the clinical privileges of a practitioner; 2. Recommendation by the Medical Executive Committee; 3. Following a formal investigation and 4. MECs that any of the following acts have occurred. For example, incompetence, or gross or repeated deviation from the standard of care, to the extent such manner as to be dangerous or injurious to any person or to the public; the use of or prescribing for or administering to himself or

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herself, any controlled substance; repeated acts of clearly excessive prescribing; or sexual misconduct with one or more patients."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Well-Being Committee" (MS 02), date 6/26/17, the P&P indicated, "The responsibility of the Well-Being Committee is advisory in nature and not a substitute for personal physician of a disciplinary body. . .It will report to the MEC and to the physician in question. . .Well-Being Committee should serve only as an advisory and monitoring body, conducting inquiries and evaluations, and making reports to the governing committee as necessary. The Committee is charged to provide support and advocacy for physicians and should not assume responsibility to report to government agencies. Of the medical staff committees responsible for credentialing, corrective action and other disciplinary matters."

During a review of the hospital's policy and procedure (P&P) titled, "Peer Review Process" (MS 8710.PR), dated 2/09/21, the P&P indicated, "The Medical Staff assess each credentialed practitioner's professional performance and behavior as part of its ongoing quality and patient safety, credentialing, privileging and corrective action responsibility, including clinical judgement, and appropriate documentation. The Chair of the Peer Review committee (PRC) will be a regular member of the Medical Executive Committee (MEC) and members will be appointed by the Chief of Staff. . Cases recommended for medical staff peer review may be generated from, the list is not all inclusive, Occurrence reports, Patient Safety Committees, Quality/Safety Departments, Risk Management Department, Midas Reporting

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process and so forth. Cases recommended for Peer Review are preliminarily screened by Peer Review (PR) Coordinator and presented to the Medical Director or Chief Medical Officer . . . If initial reviewer indicates potential conflict of interest, Peer Review (PR) coordinator will assign case to next reviewer. The Chief of Staff will make the final decision on referral to peer review. The PRC will meet monthly, evaluate cases, and make a preliminary determination which will be forwarded to the staff member for reply within 30 days. The PRC assigns a final care determination. Results of the peer review process may range from identified opportunities for enhancing care/documentation to identified opportunities of critical importance for improving care. System level opportunities or individual Practitioner issues may be identified."

During a review of the hospital's policy and procedure (P&P) titled, "Impaired Provider Policy" (MS 40), dated 5/31/18, the P&P indicated, "Substance abuse can adversely impact patient care and workplace safety. Use and abuse of alcohol and or controlled substances may impair the ability of medical staff member and advance practice providers (APP, include CRNAs, NPs, PAs, ) to provide services and may endanger the individual, his or her co-workers, patients and public. . .Whenever a hospital staff members observes evidence of possible impairment by a member pf the medical staff or APP, while on hospital premises, the staff member shall immediately inform his or her supervisor who shall inform the CEO or representative. . .he Chief of Staff or designee shall promptly conduct or supervise the administration of a Screening Physical Exam of the practitioner. . .and] ask the suspect practitioner to agree to a drug test or

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of the Chief of Staff, Vice Chief of Staff, Chair of Peer Review responsibility: recommending directly to the Board on such items as Medical Staff appointment and reappointment and Medical Staff appointment termination ... Peer Review appointed by Chief of Staff, never as a voting member, "shall review cases in which an individual patient's care has been or may have been compromised by the care provider". The Medical Bylaws further indicate the "Factors for Evaluation", which include, but not limited to clinical judgement, adherence to ethics of their profession, good character, and safely, competently perform clinical privileges, and commitment to quality care ...Whenever a serious question has been raised regarding: the clinical competence or clinical practice of any member of the Medical Staff, including care, treatment to management of a patient or patients; the safety or proper care being provided to patients; conduct by any staff member considered lower than the standard of [Facility]. The matter may be referred to the Chief of Staff, the chair of the department, the chair of the standing committee, or the CMO. If the board becomes aware of information that raises concern about any Medical Staff member shall be referred the Chief of Staff, the chair of the department, the chair of the standing committee, CMO, or the CEO to the for review and appropriate action. "The person whom the matter is referred shall conduct or arrange an inquiry which shall include the Chief of Staff to determine whether the question raised has sufficient credibility to warrant further review and, if so, shall forward it in writing to the MEC". "No action taken pursuant to this Article shall constitute an investigation". "In the event that the MEC fails to initiate an investigation in response to concerns raised about a Medical Staff

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member's competence, performance, or professional conduct in accordance with this article and the Board determines that such decisions is contrary to the weight of the evidence, the Board may direct the MEC to initiate such an investigation". "The committee conduction the investigation, the investigation committee") shall have the authority to review relevant documents and interview individual." The investigating committee "may require a physical, mental and/or behavioral examination of the individual by health care professional(s) acceptable to it." The investigating committee shall make a reasonable effort to complete the investigation and issue its report within 30 days of the commencement of the investigation". "The MEC may accept, modify, or reject any recommendations it receives from an investigating committee."

During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Rules and Regulations", dated 12/21/20, the indicated, "The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in [Facility] ...prompt and accurate completion of portions to the medical record for which he or she is responsible ... performing all other duties described in these Rules and Regulations ...Abuse and losses of controlled substance will be reported in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical service, to the Chief Executive Officer and others per medical staff policy ... Medication orders will be entered directly into the electronic medical record by the ordering physician ...accurate and complete medication reconciliation ...All verbal orders will include the

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date, and time of entry into the medical record, identify the names of the individual who gave, received and implemented the order, and then be authenticated with the date and time by the ordering practitioner".

Review of policy and procedure (P&P) titled, "Personnel management: Public Protection & Reporting Requirements", (KDEP 15), dated 11/10/14, indicated "any recognized or self-reported impairment of a staff member to the extent it affects his or her ability to practice the profession of occupation authorized by his or her license will be addressed promptly". The policy "outlined procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it effects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. . .in the interest of protecting the public, follows established procedures: Human Resource Policy HR 200, 'Drugs and Alcohol"; Administrative Policy AP 110, "Reporting Requirements for Drug Diversion, Illegal Substance Abuse or Controlled Substance Abuse", and Reporting to the California Board of Pharmacy within 14 days of receipt or development of the following information with regards to any licensed individual employed by or with the pharmacy": theft, diversion, or self-use of dangerous drugs, physical or mental impairment."

During a review of the hospital's policy and procedure (P&P) titled, "Drug Free Work Place and Drug/Alcohol testing", (HR 200), dated 4/29/2019, the P&P indicated, "The "[Facility] has

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established this policy on the use or abuse of alcohol and illegal drugs or other controlled substances by employees, contract staff or volunteers. At work or otherwise, substance abuse seriously endangers the safety of the work environment, as well as our patients and the general public ... [Facility] has established this policy to detect users and remove abusers of drugs and alcohol and to prevent the use and/or presence of these substances on the workplace. Confirmed incidents of drug diversion will be reported to the appropriate agencies ... [Facility] may suspend employees without pay under this policy pending the results of a drug test or investigation ... 'Illegal drugs or other controlled substances' means any drug or substance that is not legally obtainable; or is legally obtainable but has not been legally obtained; or has been legally obtained but is being sold or distributed unlawfully ... 'Abuse of any legal drug' means the use of any legal drug: for any purpose other than the purpose for which it was prescribes or manufactured ...'Reasonable suspicion includes suspicion that is based on specific personal observations ... information provided to management by an employee, by law enforcement officials, or by other persons believed to be reliable; or suspicion based on other surrounding circumstance ...'Drug diversion' means that an employee has the substance on his or her person or otherwise under his or her control ...Drug Use Prohibitions: violation of following will result in reporting the employee to a licensing board or agency, law enforcement agencies and /or /disciplinary action , up to and including termination of employment. The Director of Pharmacy or designee will determine the necessity of reporting to Drug Enforcement Agencies, the California Board of Pharmacy and

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Police. Human resources will report employee's licensing or certifying board as necessary. The Risk Management department will report to the California Department of Public Health as appropriate. 1. The unlawful use, sale, purchase, possession, manufacture, distribution, or dispensation of any drug or prescribed controlled substance on property or during work time is against policy ...Testing of Current Employees: Employees must submit to a drug test if reasonable suspicion exists ...Reasonable suspicion testing means drug testing based on a belief that an employee is using or has used drugs in violation of [Facility] policy. Among other things, such facts and inferences may be based upon: Direct observations ...abnormal conduct ...a report of drug use, provided by a reliable and credible source ...evidence that an employee has used, possessed, sold, solicited or transferred drugs while working or on[Facility] premises or while operating [Facility] vehicles, machinery or equipment ...Audit findings or charting issues ...Actions to be taken by Management: There may be instance where supervisors /managers have reasonable cause to believe that employee consumed drugs on [Facility] premises or reported to work under the influence of one or both. In these instances management may request a drug test ....If the employee refuse to sign the consent [for drug testing] or provide a sample, he/she will be subject to Disciplinary action up to and including termination of employment ....Drug-Free contract and follow-up testing: As a condition of employment and /or continued employment, participants in a rehabilitation program for drug and/or alcohol abuse must consent in writing via a [Facility] Drug-Free Contract to periodic unannounced testing for a period up to two (2) years after

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| A 347 | Continued From page 197<br>returning to work".<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug Diversion Illegal Substance Abuse or Controlled Substance Abuse", (AP 110), dated 8/24/20, the P&P indicated "1. When suspicious patterns of activity or other reasonable cause to suspect drug diversion is present an investigation will be initiated. 2. The Vice President, or designee, of the involved department will collaborate with Human Resources, Pharmacy, and Risk Management in investigating the suspected drug diversion. 3. Confirmed cases will be reported to: Drug Enforcement Agency- by Pharmacy; California Board of Pharmacy- by Pharmacy; Professional licensing or certifying board of the person confirmed to have diverted drugs- by Human Resources; [local] Police Department and /or other law enforcement agency- by Pharmacy; California Department of Public Health- by Risk Management. 4. Drug diversion will be considered confirmed if after investigation there is: An admission of guilt by the person suspected; Refusal to consent to drug testing or to authorize a release of the test result per Human Resource Policy HR 200 Drugs and Alcohol by the person suspected; Sufficient evidence of drug diversion to terminate the person suspected ...Evidence of patient harm or an adverse event directly related to the drug diversion".<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Medical Staff Bylaws, the P&P indicated, "Medical Executive Committee shall consist of the Chief of Staff, Vice Chief of Staff, Chair of Peer Review Committee. Responsibility: recommending directly to the | A 347 | | |

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| A 347 | Continued From page 198<br>Board on such items as Medical Staff appointment and reappointment and Medical Staff appointment termination." Well-Being Committee: "shall receive reports related to the health, well-being, or impairment of credentialed practitioners and, ...in the event information received by the committee clearly demonstrates that the health or known impairment of a Medical Staff member poses an unreasonable risk of harm to [Facility] patients, that information may be referred to the MEC for formal action." Rules for Recusal: "When determining whether recusal in a particular situation is required, the Chief of Staff or committee chair shall consider whether the Interested Member's presence would inhibit full and fair discussion of the issue." | A 347 | | |
| A 356 | ORGANIZATION OF MEDICAL STAFF<br>CFR(s): 482.22(c)(3)<br><br>[The bylaws must:]<br><br>(3) Describe the organization of the medical staff.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Medical Staff failed to ensure a supervising physician provided direct supervision to one Emergency Department Resident (physician in training, Resident 1) who was in the residency program for six months. This failure resulted in an inexperienced resident physician to care for a critically ill patient (Patient 1), which resulted in the delay of intubation (inserting a tube into the windpipe to maintain airway and help one's breathing) and mismanagement of ventilator (a breathing machine that helps the lungs working) post intubation for the patient. Patient 1 died in the Emergency Department six hours after he | A 356 | | |

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was brought in by an ambulance.

Findings:

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive [gets worse over time] lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure -a condition in which the
heart's function as a pump is not enough to supply adequate amount of blood to the body), . . .brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60 (oxygen level in the blood. A reading of 60 % [percent] or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95%) on room air, and only improved to 70 with 15 L (liters, unit of measurement) with NRB (non-rebreathing mask- a device used to assist in the delivery of higher concentration of oxygen). . .Vital signs were: HR (heart rate) 128 bpm (beats per minute), RR (respiratory rate) 40, BP (blood pressure) 138/114. High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress. . .the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing)." The ED medical record indicated Patient 1 had been switched from BIPAP to high flow nasal cannula, and back to BIPAP, which he cannot tolerate. Patient 1 remained in distress. . .struggling for air.

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During a concurrent interview and record review, on 3/23/21, at 8:35 PM, with Resident 1, Patient 1's laboratory results were reviewed. The laboratory results dated 12/21/20 at 7:19 PM, indicated, Patient 1's laboratory findings indicated: 1. High troponin 0.13 (test for heart muscle injury or heart attack, normal is 0 to 0.4), 2. High BNP 3100.70 (test for heart failure, normal less than 100), 3. Critical lactic acid 8.2 (normal 4.5 to 19.8, indicated severe problems with breathing and air exchange), 4. High carbon dioxide (waste product of breathing oxygen) and 5. Low oxygen blood levels. The first two indicate heart muscle injury and heart failure; and the latter three reflected respiratory failure (not have enough oxygen to sustain life and needs a breathing tube). Resident 1 verified the findings. Resident 1 stated, "no thoughts about the lab or ECG results. . for a critically ill patient. . .Resident 1 stated he did not discuss the labs with MD 5.

During a review of Patient 1's "All Active Orders" (AAO), dated 12/21/20, it was noted there were no orders from ED Resident 1 or Supervising Physician to switch Patient 1 between BiPAP and a non-rebreather mask.

During an interview on 3/23/21, at 8:36 PM, with Resident 1, Resident 1 stated, "Patient 1 was critically ill. . .I was very nervous about caring for him. . .[Patient 1] was very sick." Resident 1 documented, "patient was not tolerating BiPAP ...and says he [Patient 1] would prefer intubation to BIPAP".Resident 1 stated, he did not communicate with MD 5 about his concerns.

During a concurrent interview and record review, on 3/23/21, at 8:48 PM, with Resident 1, Patient

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1's ED Documentation dated 12/21/20, was reviewed. The ED medical record indicated, "Patient 1 had "exacerbation of CHF [heart failure] ...acute renal failure [kidneys stop functioning normally], cardiogenic shock [heart not able to pump enough blood to sustain life]." Resident 1 verified the findings.

During an interview on 3/25/21, at 7:05 PM, with Respiratory Therapist (RT 1), RT 1 stated, [Patient 1's laboratory results were "horrible", and Patient 1 was "voicing 'can't breathe' and struggling for air. . .for breathing tube." For several hours, RT 1 stated, she was "in and out of the room. . .Patient 1 was in distress. . .deteriorating. . .desating [desaturation, oxygen levels falling below normal]. . .BiPAP didn't work and not tolerated." RT 1 stated on Patient 1's behalf she "advocated intubation multiple times" and discussed intubation with Resident 1 and MD 5. RT 1 stated RN 1 was doing the same.

During a concurrent interview and record review, on 3/25/21, at 8:15 PM, with Registered Nurse 1 (RN 1), Patient 1's Emergency Documentation was reviewed. The ED Notes indicated RN 1 and Respiratory Therapist (RT 1), both advocated for intubation for Patient 1. RN 1 stated, "Patient 1 was having a "hard time breathing. . .not improving. . .difficult getting sat [oxygen level from SP02 monitor]. . .Patient 1 couldn't breathe." RN 1 verified there were no physician orders for oxygen therapy, oxygen delivery mode, vital signs or parameters to adjust medications that maintain blood pressure and heartrate.

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, the Emergency Documentation record indicated, "Resident 1

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intubated the patient at 10:02 PM with MD 5 present in the room."

During a concurrent interview and record review, on 3/23/21, at 9 PM, with Resident 1, Patient 1's ED medical record was reviewed. Resident 1 stated, he intubated [Patient 1] at 10:02 PM, but could not state the ventilatory requirements for an intubated patient. Resident 1 stated, he "did not order oxygen." Resident 1 stated, "don't know who orders oxygen...didn't discuss [patient] oxygen needs with (MD 5) ...don't know why I should ...didn't order ventilator settings ....don't know who would ... don't know who should order a ventilator or oxygen." Resident 1 stated, Patient 1 was "on 100% oxygen then later said, "that was an assumption when I said [Patient 1] was on oxygen." Resident 1 reviewed Patient 1's medical record and stated, "I do not see it documented." Resident 1 stated, he could "not recall' if Patient 1 was placed on a ventilator."

During an interview on 3/23/21, at 3:46 PM, with Emergency Physician attending/supervising physician (MD 5), MD 5 stated, "Resident 1 was taking care of Patient 1." MD 5 stated he could "not recall" if he or Resident 1 gave "verbal orders" for a ventilator and ventilator settings." MD 5 stated, he did not write orders for a ventilator, ventilator settings or oxygen therapy. MD 5 stated, he left Patient 1's room after intubation because he was "running from room to room ...running codes." MD 5 stated, he was unable to find documentation of the orders for ventilator settings, oxygen to be delivered, or repeated blood gases. At 5:10 PM, MD 5 stated, "Resident 1 is a learner."

During a concurrent interview and concurrent

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record review, on 3/23/21, at 6:15 PM, with the Emergency Department Nurse Manager (EDNM), Patient 1's Emergency Documentation was reviewed. EDNM was unable to locate documentation regarding oxygen therapy orders, ventilator orders, ventilator use, ventilator settings or Patient 1's response to intubation.

During a concurrent interview and record review, on 3/23/21, at 7:45 PM, with Director of Respiratory Services (DRS), Patient 1's Emergency Documentation was reviewed. The record indicated RT 1 was present for Patient 1's intubation. The intubation was completed by Resident 1 and MD 5. DRS was unable to locate any documentation regarding oxygen use, bag masking (method of providing oxygen via a hand-held device), ventilator orders, ventilator settings or Patient 1's response to intubation, and respiratory assessment.

During a concurrent interview and record review on 3/23/21, at 9:07 PM, with Resident 1, Patient 1's post intubation documentation was reviewed. It was noted there were no orders by the physicians on the ventilator settings. Resident 1 stated a ventilator is required after Patient 1's intubation. Resident 1 stated, he did not order the ventilator, oxygen therapy, or the ventilator settings. Resident 1 stated, he did not know who would be responsible for the orders.

During an interview on 3/24/21, at 3 PM, with Emergency Physician (MD 6), MD 6 stated "first year residents put orders in the electronic health record. . .No verbal orders by residents" are allowed. MD 6 stated, a patient who has been intubated "requires oxygen and a ventilator. . . Ventilator, ventilator settings and oxygen are

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ordered by the physician. ED residents should know what is needed for intubation-- oxygen, a ventilator, and ventilator settings." MD 6 stated, the ED residents have "training" on ventilators and intubation before they are allowed to provide these procedures.

During an interview on 3/25/21, at 8:50 PM, with RN 1, RN 1 stated, she could not "recall if [Patient 1] was placed on a ventilator. RN 1 stated, a portable BiPAP machine was used for Patient 1's BiPAP, and the machine could not be used as a ventilator. RN 1 stated she could not locate any physician orders for vital signs, oxygen therapy, ventilator or ventilator setting. RN 1 stated, RT should have documented "ventilator and settings and provided respiratory care".

During an interview, on 3/31/21, at 10:30 AM, with ED Resident PGY 2 (Resident 8), Resident 8 stated patients who require oxygen therapy, need a physician order. Resident 8 stated first year resident need direct supervision, second and third year residents require "indirect supervision for just about anything."

During a concurrent interview and record review, on 4/1/21, at 10:59 AM, with the Director of GME (Graduate Medical Education), the Resident Capability spreadsheet was reviewed. The Director of GME stated, there were three levels of supervision for residents based on the review by the faculty's determination. The Director of GME stated, ED Resident 1 was in the program only six months and required a lot of direct supervision. The Director of GME stated, direct supervision meant the supervising physician should have direct view of the resident and is physically present with the resident. The Director

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| A 356 | Continued From page 205<br>of GME stated, the first year residents were to learn to document their own notes and maintain communication with their supervising physician.<br><br>During a review of the hospital policy and procedure (P&P) titled, "Medical Staff Rules and Regulations", dated 12/21/20, the P&P indicated, "The responsibility of the attending physician, he/she "will be responsible for the medical care and treatment of the patient while in [Facility] ...prompt and accurate completion of portions to the medical record for which he or she is responsible ... performing all other duties described in these Rules and Regulations. . . Medication orders will be entered directly into the electronic medical record by the ordering physician ...accurate and complete medication reconciliation ...All verbal orders will include the date, and time of entry into the medical record, identify the names of the individual who gave, received and implemented the order, and then be authenticated with the date and time by the ordering practitioner". | A 356 | | |
| A 398 | SUPERVISION OF CONTRACT STAFF<br>CFR(s): 482.23(b)(6)<br><br>All licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the | A 398 | | |

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hospital failed to:

1. Ensure performance evaluations for four of 12 staff members: Respiratory Therapist (RT)1, Registered Nurse (RN) 2, RN 13, and House Supervisor (HS) were completed in a timely manner. This failure had the potential to affect patient care when employees' performance evaluations were not communicated or analyzed to ensure employees meet the requirements of the position and function in accordance with the goals and expectations of the organization.

2. Ensure staff training and demonstration of competency (a person's ability to perform various tasks or skills at a target proficiency level) on Medication Administration for three of six Registered Nurses (RN 1, RN 3, and EDNM [ED Nurse Manager]) in the Emergency Department were completed. This failure resulted in the Propofol (sedation medication) drip left unattended and not discarded timely, which was later inadvertently accessed and used improperly.

Findings:

1. During a concurrent interview and personnel record review, on 3/29/21, at 2:50 PM with the Director of Human Resources (DHR), Respiratory Therapist (RT) 1's "personnel record" was reviewed. The personnel record indicated RT 1 was hired on 3/24/14. The latest performance evaluation was completed on 8/5/20. DHR stated performance evaluations should be completed at least close to the date of hire unless the employee transferred to another unit, changed position, promoted, or took a leave, then the employee evaluation date will change. DHR verified the findings and stated this evaluation is

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late, at least five months late.

During a concurrent interview and personnel record review, on 3/31/21, at 11 AM, with DHR, Registered Nurse (RN) 2's "personnel record" was reviewed. The personnel record indicated RN 2 was hired on 7/16/18. The latest performance evaluation was completed on 10/21/20. DHR verified the findings and stated this evaluation is late, at least three months late.

During a concurrent interview and personnel record review, on 3/31/21, at 11:30 AM, with DHR, RN 13's "personnel record" was reviewed. The personnel record indicated RN 13 was hired on 11/16/15. The performance evaluation was completed on 12/18/19. DHR verified the findings.

During a concurrent interview and personnel record review, on 3/31/21, at 4:50 PM, with DHR, House Supervisor (HS)'s "personnel record" was reviewed. The personnel record indicated HS was initially hired on 1/7/02 but took a military leave, which changed his hire date to 3/20/02. The performance evaluation was completed on 5/15/20. DHR verified the findings and stated, this evaluation is also late, at least two months.

During a review of the hospital's policy and procedure (P&P) titled, "Performance Management and Competency Assessment Program," dated 12/19/19, the P&P indicated, "

2. During an interview on 3/29/21, at 3:15 PM, with the Emergency Department Clinical Educator (EDCE), EDCE stated Medication Administration is one of the competencies for all of the registered nurses working in the ED.

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| A 398 | Continued From page 208<br>During a concurrent interview and personnel record review, on 3/29/21, at 3:30 PM, with DHR, RN 1's "personnel record" was reviewed. The "personnel record" indicated, "RN 1 did not complete her Medication Administration competency due 3/21/21." DHR verified the findings.<br><br>During a concurrent interview and personnel record review, on 3/29/21, at 4 PM, with DHR, RN 3's "personnel record" was reviewed. The personnel record indicated, "RN 3 did not complete her Medication Administration competency due 3/21/21. DHR verified the findings.<br><br>During a concurrent interview and personnel record review, on 3/29/21, at 4:15 PM, with DHR, EDNM's "personnel record" was reviewed. The personnel record indicated, "EDNM did not complete his Medication Administration competency due 3/21/21. DHR verified the findings.<br><br>During a review of the facility's policy and procedure (P&P) titled, "Competency: Nursing Services," dated 8/16/19, the P&P indicated, "VI. Annual Competency Evaluation B. individual competency is evaluated annually during the staff member's performance appraisal process based on the job description and the unit-specific identified competencies required for the job. The Core Curriculum Pathway is utilized as a guide for individual staff development expectation in specific clinical settings." | A 398 | | |
| A 405 | ADMINISTRATION OF DRUGS<br>CFR(s): 482.23(c)(1), (c)(1)(i) & (c)(2) | A 405 | | |

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| A 405 | Continued From page 209<br>(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.<br><br>(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.<br><br>(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Hospital failed to:<br>1. Develop policies and procedures for the safe administration and handling of Propofol (sedation medication) for two of 72 sampled patients (Patient 1 and Patient 2).<br><br>This failure resulted in Patient 1's Propofol drip to be left in an IV pole unattended, which led to Patient 2's inadvertent use and access of the drug, which then later resulted in Patient 2's death.<br><br>2. Follow its policy and procedure on Medication Administration for two of 72 sampled patients (Patient 22 and Patient 20) when: | A 405 | | |

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A. There were delays in documenting nursing independent double check (means two licensed nurses independently checked if medication was administered safely and accurately) for IV (into vein) insulin (a medication to control the blood sugar, and a high risk drug (drugs that pose highest risk of harm if not used properly) prescribed for Patient 22.

B. Nursing staff did not follow physician's order for Patient 20's medication parameters (set of measurement numbers used to monitor patients progress toward a goal).

These failures had the potential for unsafe medication use and monitoring practices.

Findings:

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive [gets worse over time] lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure -a condition in which the heart 's function as a pump is not enough to supply adequate amount of blood to the body), . . .brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60 (Oxygen level in the blood. A reading of 60 mmHg or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95% [percent]) on room air, and only improved to 70

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with 15 L (liters, unit of measurement) NRB (non-rebreathing mask- a device used to assist in the delivery of higher concentration of oxygen). . .Vital signs were: HR (heart rate) 128 bpm (beats per minute), RR (respiratory rate) 40, BP (blood pressure) 138/114. High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress. . .the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing), high flow nasal cannula, and eventually taking off the NRB mask. Patient was then later intubated for respiratory failure and inability to tolerate BIPAP."

During a review of Patient 1's "Critical Care Progress Notes" (CCPN), dated 12/21/20, at 11 PM, the CCPN indicated, "In the emergency department, [Patient 1] was found to be hypotensive (low blood pressure), tachypneic, (rapid respiratory rate), and tachycardic (rapid heart rate). The Intensive Care Unit (ICU) Team was consulted and the team requested for patient to undergo CTA (Computerized Tomography Angiography- an imaging test that looks at the arteries that supply blood to one's heart) for possible PE (pulmonary embolism -a condition in which a blood vessel in the lung(s) gets blocked by a blood clot). While in the ED, [Patient 1] was reported to have a wide-complex rhythm. The patient coded (medical emergency in which one is found to be unresponsive, pulseless, and not breathing) and after 10 minutes and five rounds of CPR (cardiopulmonary resuscitation - an emergency lifesaving procedure performed when the heart stops beating), achieved return of spontaneous circulation (ROSC). Patient 1 was placed on Propofol drip, 2000 mg in 100 ml

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(mililiter, a unit of measurement) at 5mcg/kg/min (micrograms per kilogram per minute - units of measurements) for post-intubation sedation."

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 11:19 PM, the Reexamination/Reevaluation Notes and Resident Attestation documented by MD 5 indicated, ". . .ED RN reported wide complex rhythm on the monitor and she noted no pulses. Compressions started immediately. Epi/Bicarb/Amiodarone (emergency life-saving medications) given. ROSC (return of spontaneous circulation) after approximately 10 minutes of downtime. On 12/22/20, at 1:54 AM, MD 7 documented MD 5 discussed the patient's care with [Patient 1's] sister extensively, and per his sister's wishes, placed [Patient 1] on Comfort Care Status. MD 7 administered Fentanyl (narcotic pain medication) 100 mcg. IV (intravenous-into the vein), withdrew the endotracheal tube (a flexible plastic tube that is placed through the mouth into the trachea (windpipe) to open the airway and help a patient breathe), and mechanical ventilation (a machine that helps a patient breathe), and vasopressor (any medication that tends to raise low blood pressure) support. MD 7 pronounced Patient 1 dead at 1:53 AM."

During an interview on 3/22/21, at 9:30 PM, with Registered Nurse (RN) 1 and Emergency Department Nurse Manager (EDNM), RN 1 stated, "I started a Propofol drip 2000 mg (miligram, a unit of measurement) in 100 ml (mililiter, a unit of measurement) bottle on 12/21/20, at 10:07 PM. Two minutes later, at 10:09 PM, I stopped the drip because I could not get [Patient 1's] blood pressure. I spoke with

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Resident 1 who was managing the patient, but I could not recall what Resident 1 said, and I did not get an order, and I did not chart. As soon as I paused the Propofol drip, I was trying to keep the patient alive, which she described as going in and out of the room to get the "pressors" (medications to increase the blood pressure) from the pneumatic tube system (a fast, simple, secure, and reliable way of transporting small objects in relatively large distances). I did not ask [Resident 1] what I need to do with the Propofol drip, whether to hold it or to discontinue the drip, and I did not receive a doctor's order. I was so busy I left the Propofol drip on the IV pole. The Propopfol drip was discontinued and taken down on 12/22/20 at 3:06 AM, after Patient 2's demised. On 3/22/21 at 10:10 PM, in retrospect, RN 1 stated, "Once Propofol is discontinued, I would take it down, go to the med room and waste it." EDNM verified the findings.

During an interview on 3/23/21, at 6 PM, with EDNM, EDNM stated, "I was called at 2:30 AM. The staff explained [Patient 2] was found down in the restroom. They did CPR and was not able to revive him. I was told they found two syringes with white substances. He injected himself with Propofol that caused his demise."

During an interview on 3/23/21, at 6:30 PM, with RN 2, RN 2 stated, "The bathroom door was locked for several hours. Security guard had to unlock the bathroom door. RN 16 and I saw someone on the floor, who appeared to have been down for a while. The person was sitting on the floor, with his face forward, hunched over on his knees, with his face on the ground on the toilet. He was dark blue in color. When we rolled him over, he was cold to the touch. RN 1, RN 2,

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RN 16, and I were in the bathroom. RN 1 and RN 2 called a code. We recognized the person, [Patient 2 was SC 1]. That night [Patient 2] was not acting himself, he was distant; normally, he was outgoing and bubbly." At 6:40 PM, RN 2 stated, "We found two 20-30 ml syringes; one empty syringe next to his body and the other one was full with a needle."

During an interview on 3/29/21, at 8:50 PM, with RN 1, RN 1 stated, "After [Patient 2] passed that's when I took down the Propofol. I noticed 3/4 of the bottle of Propofol was empty. I called RPHED [Clinical Pharmacist ED] and RN 3 to discuss the missing Propofol. I left [Patient 1's] room several times after I stopped the Propofol. Patient 1 was left alone and unattended."

The hospital policy and procedure on Propofol administration and safe handling was requested but none was provided. EDNM acknowledged there was no written Propofol policy and procedure.

During a review of the hospital's policy and procedure (P&P) titled, "Medication Administration," dated 6/19/19, the P&P indicated, "14. HOLD Orders are intended to interrupt therapy for a short period of time due to changes in the patient's condition or pending procedures. Orders on HOLD by the prescriber without a specified duration or number of doses will be discontinued unless further orders are received to resume, discontinue, or modify the medication."

2A. During a concurrent observation and interview, on 3/24/21, at 10: 49 AM, in

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Cardiovascular Intensive Care Unit (CVICU-a unit in the hospital for patients with heart problems) with Registered Nurse (RN 17), RN 17 was observed adjusting IV insulin dose for Patient 22. He measured patient's blood sugar and used a computerized software program called Glucommander, which directed the insulin dosage adjustment based on doctor's order. RN 17 subsequently, changed the setting on the pump for a new dose of insulin delivered into the patient's body. RN 17 then, asked Registered Nurse (CVICUM-Cardiovascular ICU Manager) to double check the insulin dosage change in both the computer and on the drug pump (a device that helped with safe delivery of medication into the body). RN 17 stated that he measured the blood sugar every hour to keep a tight control of insulin dose based on doctor's order.

During a review of Patient 22's "Physicians Order" (PO), on 3/26/21, at 11:29 AM, with Registered Pharmacist-IT ( RPHIT, a pharmacist with computer background) and RN 5, the doctor's order, dated 03/15/21, indicated, for insulin use check blood sugar every hour to keep Patient 22's blood sugar numbers between 100-140 mg/dl ( "mg" and "dl" are unit of measure). The medical record documentation for blood sugar and independent double check from 3/17/21 to 3/18/21 showed 2 to 8 hours delay in documentation's as follows:

3/17/21: Insulin dose adjustment recorded at 04:26 AM for a 23:28 PM dose on 3/16/21
3/17/21: Insulin dose adjustment recorded at 04:26 AM for a 00:49 AM dose on 3/17/21
3/17/21: Insulin dose adjustment recorded at 04:26 AM for a 02:00 AM dose on 3/17/21
3/17/21: Insulin dose adjustment recorded at

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14:50 PM for a 6:50 AM dose on 3/17/21
3/18/21: Insulin dose adjustment recorded at 05:30 AM for a 20:00 PM dose on 3/17/21

Patient 22's insulin adjustments records indicated, the blood sugar drawn on 3/17/21, at 2:50 AM, was 76 mg/dl and was not within the targeted range as ordered by the medical doctor. The review, additionally, indicated the next blood sugar was drawn two and one-half hours later at 5:31 AM when doctor's order was to check the blood sugar every hour. Patient 22 experienced low level of blood sugar between 62 to 67 mg/dl (which was less than target range of 100-140 mg/dl and required treatment) on 3/17/21 at 6:49 AM, 7:12 AM, and 7:39 AM. The treatment included stopping the Insulin and use of rescue medication (same as antidote- or use of concentrated sugar to counter insulin effect) to help normalize the blood sugar to the desired range of 100-140 mg/dl. There was no explanation for the delays in redrawing the blood sugar after a lower than normal blood sugar level was obtained.

During an interview, on 3/29/20, at 3:34 PM, with RN 18 in the Intensive Care Unit (ICU a unit in the hospital where most critical patients are cared for), RN 18 stated independent double check of a high-risk medication should have happened at the time of double verification. RN 18 added, the nurse should have documented changes to medication monitoring parameter in the medical record.

During an interview, on 3/30/21, at 9:22 AM, with ICU Nursing Director (DICU), DICU stated the independent double check should be documented by nursing staff before any dosage change for

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hospital's designated high risk medications (medication that could pose significant harm if not administered correctly). DICU added, the double check included the pump setting for dosage change and the vital signs (vital signs are clinical measurements, such as mental alertness, temperature, or blood sugar that indicated the state of a patient's essential body functions) ordered by the doctor.

During a review of the hospital's policy and procedure (P&P) titled, "Documentation, Nursing: Acute Patient Care", dated 12/15/20, the P&P indicated, "Nursing documentation should reflect communications, observations, decisions, actions and outcomes related to patient centered care. Information reflecting the nursing process, patient plan of care and other pertinent information should be documented in the individual patient record in an ongoing accurate, timely and legible manner. . .Principles of Documentation: When to chart: To record nursing action and individual responses as soon after they occur as possible."

2B. During a review of Patient 20's Physicians Orders, with RPHIT and RN 5, the physician's order, dated 3/13/21, indicated, "Fentanyl (a sedative narcotic medication) 2,500 mcg in 250 mL ("mcg' and "ml" are unit of measures) of Sodium Chloride 0.9% (a base solution to mix the medication) IV (into the vein) to keep the patient sedated ...Adjust by 25 mcg/hr every one hour (hr). Maximum dose: 200 mcg/hr, Goal: RASS -2 to 0 (RASS stands for Richmond Agitation and Sedation Scale, a validated and reliable method to assess patients' level of drowsiness; -2 [light sedation] to 0 [alert, calm)])."

During a concurrent interview and review of

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Patient 20's Medication Administration Record (MAR) with RPHIT and RN 5, the MAR dated 3/13/21, indicated, from 10:54 AM to 12:15 PM, the fentanyl dose was increased in 25 mcg/hr increments from 25 mcg/hr to 175 mcg/hr every 15 minutes. The doctor's order indicated dosage change to be done every one hour based on RASS score. RPHIT and RN 5 verified the findings.

During a review of Patient 20's Fentanyl monitoring parameter record, on 3/29/21, at 4:06 PM, with RPHIT and RN 5, RPHIT and RN 5 were unable to find RASS score documented in the chart for 12 hours (3/13/21 at 6 PM until 3/14/21 at 6 AM). On 3/14/21 (6 AM - 5 PM) nursing documented a RASS score of -5 (minus 5, which means unresponsive to voice or physical stimulation) with no dosage modification for fentanyl. On 3/14/21, (6 PM - 12 AM) RASS score was not documented in the medical record and the fentanyl dosage was continued at 200 mcg/hr.

During an interview, on 3/30/21, at 9:22 AM, with ICU Nursing Director (DICU), DICU stated nursing staff collaborated with medical doctors that were stationed in the unit to address changes in patient's condition or the medication needs of the patients. DICU added, nursing staff should follow the parameters set by doctor's order and if the standard medication orders did not fit the specific needs of the patients, the nurses should have contacted the medical doctor for new order or parameters. Additionally, nursing staff should have documented any communication with medical doctor verbally or over the telephone in the medical record.

During a review of the hospital's policy and

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| A 405 | Continued From page 219<br>procedure (P&P) titled, "Documentation, Nursing: Acute Patient Care", dated 12/15/20, the P&P indicated, "Nursing documentation should reflect communications, observations, decisions, actions and outcomes related to patient centered care. Information reflecting the nursing process, patient plan of care and other pertinent information should be documented in the individual patient record in an ongoing accurate, timely and legible manner. . .Principles of Documentation: When to chart: To record nursing action and individual responses as soon after they occur as possible." | A 405 | | |
| A 467 | CONTENT OF RECORD: ORDERS,NOTES,REPORTS<br>CFR(s): 482.24(c)(4)(vi)<br><br>[All records must document the following, as appropriate:]<br>All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the Hospital failed to:<br><br>1. Ensure Registered Nurse (RN) 1 documented in the medical records vital signs, nursing assessment, nursing notes, physician's orders, and report of treatment for one of 72 sampled patients (Patient 1) when Patient 1's condition started to decline up to the time when Patient 1 "coded" (a medical emergency in which one is found to be unresponsive, pulseless, and not breathing), and the medication propofol (used for | A 467 | | |

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sedation) drip was administered intravenously (IV, given through a tube directly into a vein, also known as a "drip"), stopped, and left unattended on an IV pole in Patient 1's room. This failure had the potential for clinicians to miss pertinent information necessary for safe and appropriate care and monitoring of Patient 1's condition.

2. Ensure First Year Resident (Resident 1) and Attending/Supervising Physician (MD 5) documented their physician's orders and other pertinent clinical information for one of 72 sampled patients (Patient 1) during his care in the Emergency Department. This failure had the potential for missed information, which could adversely affect patient care when physician orders are verbally ordered and not documented.

Findings:

1. During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure -a condition in which the heart's function as a pump is not enough to supply adequate amount of blood to the body) . . . brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60% (% of oxygen level in the blood, 60% or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95% on room air), and only improved to 70% with 15 L (liters, unit of measurement) NRB (non-rebreathing mask- a

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device used to assist in the delivery of higher concentration of oxygen). . . Vital signs were: HR (heart rate) 128 bpm (beats per minute, normal is about 60-100), RR (respiratory rate) 40 (normal is about 12-18), BP (blood pressure) 138/114 (normal is about 120/80). High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress. . . the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing), high flow nasal cannula, and eventually taking off the NRB mask. Patient was then later intubated (a tube is inserted down the throat and into the windpipe to assist with breathing) for respiratory failure and inability to tolerate BIPAP."

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 11:27 PM, the Critical Care Notes documented by MD 5, indicated, ". . . There was an acute impairment of an organ system with a high probability of imminent or life threatening deterioration in the patient's condition. . . present hypoxic (lack of oxygen in the brain), anxious with increased work of breathing. He was speaking 2-3 word word sentences. He remained on respiratory distress at 15 LPM (liters per minute) oxygen. We attempted BIPAP and High Flow which he did not tolerate. . . Patient became more and more agitated. ED (Emergency Department) RN reported BP dropping. Dobutamine (medication to increase blood pressure) started 2nd BIPAP failed. . ."

During a review of Patient 1's "Critical Care Progress Notes," dated 12/21/20, at 11 PM, the Critical Care Progress Notes indicated, "In the emergency department, [Patient 1] was found to

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be hypotensive (low blood pressure), tachypneic, (rapid respiratory rate), and tachycardic (rapid heart rate). The Intensive Care Unit (ICU) Team was consulted and the team requested for patient to undergo CTA (Computerized Tomography Angiography- an imaging test that looks at the arteries that supply blood to one's heart) for possible PE (pulmonary embolism -a condition in which a blood vessel in the lung(s) gets blocked by a blood clot). While in the ED, [Patient 1] was reported to have an wide-complex rhythm (a potentially serious type of heartbeat). The patient coded and after 10 minutes and five rounds of CPR (cardiopulmonary resuscitation - an emergency lifesaving procedure performed when the heart stops beating), achieved return of spontaneous circulation. Patient 1 was placed on Propofol drip, 2000 mg (milligram, a unit of measurement) in 100 ml (milliliter, a unit of measurement) at 5 mcg/kg/min (micrograms per kilogram per minute - units of measurements) for post-intubation sedation."

During a concurrent interview and record review on 3/25/21, at 9:31 PM, with RN 1 and Emergency Department Nurse Manager (EDNM), Patient 1's "ED Flowsheet" was reviewed. The flowsheet indicated the last documented vital signs were taken on 12/21/20 at 9:15 PM. The vital signs were: BP 132/70 (right leg), HR 107, RR 40, Non-rebreather mask, Oxygen saturation 90%. RN 1 stated, Patient 1 "was placed on non-rebreather mask, alternating BIPAP, high flow nasal cannula but the patient was not tolerating the different oxygen therapies." RN 1 and EDNM were unable to find documentation in the medical record of the doctor's orders for the different oxygen therapies used, nursing documentation of the condition of the patient, and

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oxygen saturation level every time oxygen therapy was changed. RN 1 stated, "[Patient 1] continued to have difficulty breathing and could not speak full sentences but I did not document my assessment and my communication with the doctor."

During an interview on 3/25/21, at 9:45 PM, RN 1 stated, "The patient's blood pressure dropped immediately after the Propofol drip was started. I started the Propofol drip at 10:07 PM and stopped it at 10:09 PM. I cannot recall what Resident 1 said but I did not get an order to stop the Propofol, nor to hold, or discontinue the drip. I did not ask Resident 1 what to do with the Propofol drip once I stopped it. I got so busy trying to save the patient's life. I was in and out of the room getting the medications for his blood pressure from the pneumatic tube system (a fast, simple, secure, and reliable way of transporting small objects in relatively large distances). The Propofol was left hanging on the IV pole and was left unattended."

During an interview on 3/25/21, at 9:53 PM, with EDNM, EDNM stated, "The doctor did not order monitoring parameters. The nurse does not have to be in the room when the Propofol drip is running. There are not enough nurses to sit in the room with the patient."

During an interview on 3/25/21, at 9:55 PM, with RN 1, RN 1 stated, "Patient 1 had an ESI 1 (Emergency Severity Index - a five-level, emergency department triage program relied upon by nurses to assess patient acuity based on their presentation in the ED and the expected level of care). RN 1 stated, "ESI 1 means the patient is critical. During that time, I had three

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patients, [Patient 1], one in Room 20, and one in the hallway awaiting for admission bed."

During a review of Patient 1's "Medication Administration Record" (MAR), dated 12/21/20, the MAR indicated,"Propofol was administered at 5 mcg/kg/min at 10:07 PM and Propofol was discontinued at 10:09 PM."

During a concurrent interview and record review, on 3/25/21, at 10 PM, with RN 1 and EDNM, Patient 1's "Emergency Documentation Nursing Assessment Flowsheet" was reviewed. RN 1 and EDNM were unable to find documentation of a baseline assessment for level of consciousness, restlessness, agitation, anxiety, vital signs, and pain level prior to administration of Propofol. RN 1 and EDNM were unable to find documentation that RN 1 validated the physician's desired level of sedation. RN 1 stated we (referring to ED nurses) use RASS [(Richmond Agitation-Sedation Scale - a medical scale used to measure agitation or sedation level of a person. RASS is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative]), one level to denote a calm and alert state (0), and 5 levels of sedation (-1 to -5) culminating in unarousable (-5)]. The record indicated RASS Score was documented on 12/22/20, at 1:41 AM at -2 (light sedation). RN 1 and EDNM verified there were no documentation of RASS Scores from 12:32 AM until 1:41 AM.

During a review of the hospital's policy and procedure (P&P) titled, "Documentation, Nursing Acute Patient Care," dated 12/15/20, the P&P indicated, "Nursing documentation should reflect communications, observations, decisions, actions, and outcomes related to patient-centered

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care. . .A. When to Chart 1. To record nursing actions and individual responses as soon after they occur as possible. . .B. What to Chart 1. Symptoms, 2. Observations, 3. . .unusual health situations until resolved, 4. Contacts with and outcomes of interactions with primary care providers. . .6. Changes in condition and follow up actions/responses to symptoms or condition changes. . .II. A. The RN will perform initial and subsequent assessments according to established guidelines and standards of care. . .C. Nursing documentation should reflect assessment findings and depict both clinically significant normal findings as well as abnormal per the clinician's clinical judgment. . ."

2. During a concurrent interview and record review on 3/23/21, at 8:30 PM, with Resident 1, Patient 1's "Emergency Documentation" dated 12/21/20, was reviewed. Resident 1 was unable to find documentation of his orders for the different oxygen treatments Patient 1 was placed on, monitoring parameters for propofol, reassessment of Patient 1's condition when Patient 1's blood pressure dropped dangerously low, and an order to stop, hold, or discontinue the propofol. Resident 1 stated, "[Patient 1] came in by Emergency Medical Services (EMS) Code 1, [which means] the Provider needs to see the patient immediately. MD 5 and I were in the room to stabilize the patient. [Patient 1] was short of breath, tachypneic at 40, tachycardic at 128 bpm." Patient 1's laboratory results were reviewed and indicated critical results. Resident 1 stated, "I doubt if I documented the labs." The electrocardiogram (EKG) was reviewed and indicated, "atrial flutter (abnormal, irregular heart beat at a rapid rate) HR 135." Resident 1 stated, I had no thoughts about it. Resident 1 stated,

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"Patient 1 was critically ill. He was unable to tolerate BIPAP. I gave him Ativan (sedation medication) 1 mg to calm him down. [Patient 1] was placed on BIPAP, NRB, High Flow Oxygen but he did not tolerate it. At 10 PM, [Patient 1] was intubated by me with MD 5 at the bedside. He was started on propofol drip at 10:07 PM for post-intubation sedation and the drip was stopped, two minutes later, at 10:09 PM because Patient 1's blood pressure dropped as reported by RN 1. At 8:47 PM, Resident 1 stated, "I felt very nervous taking care of a critically ill patient."

During an interview on 3/25/21, at 9:31 PM, with RN 1, RN 1 stated, Resident 1 was in Patient 1's room at 10 PM [on 12/21/20]. Patient 1 had just been intubated. RN 1 stated she received an order from Resident 1 to start Propofol 2000 mg in 100 ml at 5 mcg/kg/min. RN 1 stated, "I started the Propofol drip at 10:07 PM and stopped it two minutes later, at 10:09 PM. I reported to Resident 1 that Patient 1's blood pressure dropped. I don't remember Resident 1 coming in to assess Patient 1. There was no verbal or written physician's order to stop, hold, or discontinue Propofol."

During a review of Patient 1's "Physician's Order," dated 12/21/20, at 10:01 PM, the Physician's Order indicated, "Resident 1 ordered Propofol 2000 mg in 100 ml at 5 mcg/kg/min. Adjust by 5 - 10 mcg/kg/min every 5 minutes. Goal -2 to 0."

During a review of the hospital's policy and procedures (P&P) titled, "Medical Staff Rules and Regulations," dated 12/21/20, the P&P indicated, "3.2 Content and Timeliness of Medical Record Documentation: a) Responsibility of Attending Physician: the attending physician or his/her

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| A 467 | Continued From page 227<br>representative shall be responsible for the preparation of a complete medical record for each patient. The attending physician of record is ultimately responsible for completing the medical record. b) General Requirements: . . . 12. diagnostic and therapeutic orders, procedures, test, and results. . . 14. medications ordered, prescribed, or administered. . . 19. relevant observations, diagnoses, or conditions established during the course of care, treatment, and services. . . d) Medical Orders: 1) orders will be entered directly into the electronic medical record by the ordering practitioner utilizing CPOE (Computerized Physician/Provider Order Entry- an application that allows health care providers to use a computer to directly enter medical orders electronically in inpatient and ambulatory settings). . . 4.8. Orders for Oxygen Services: Oxygen is a medication and should be prescribed by dosage, time, and method. . . Progress notes: Clinically pertinent progress notes shall be recorded at the time of observation, and must be legible, dated, and timed, shall be documented with a frequency consistent with the acuity of medical problems to reflect patient's condition and plans for management, and shall always be written in a manner with such clarity and frequency that another Practioner could quickly understand the [patient's status. . . Any complications must also be documented. . ." | A 467 | | |
| A 489 | Condition of Participation: Pharmaceutical Se<br>CFR(s): 482.25<br><br>§482.25 Condition of Participation: Pharmaceutical Services.<br><br>The hospital must have pharmaceutical services that meet the needs of the patients. | A 489 | | |

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| A 489 | Continued From page 228<br>The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.<br>This CONDITION is not met as evidenced by:<br>Based on observation, interview, and record review the hospital failed to ensure safe pharmaceutical services were provided and met the needs of each patient as evidenced by:<br><br>1. The hospital failed to ensure performance evaluation (or performance review, a formal assessment in which a manager evaluates an employee's work performance, identifies strengths and weaknesses, offers feedback, and sets goals for future performance) for pharmacy technicians (pharmacy technician worked under the supervision of a pharmacist to accurately prepare and distribute medications) were reviewed and signed by a pharmacist in leadership position for two of three sampled pharmacy staff members (RXT 1 and RXT 2 ). This failure had the potential for unsafe oversight of pharmacy technician's performance when it was not communicated and evaluated by a licensed pharmacist in leadership position. (Refer to A0491)<br><br>2. The hospital failed to:<br>A. Implement a system to ensure that all controlled drug waste had been accurately reconciled and accounted for five of eight sampled patients (Patient 26, Patient 27, Patient 28, Patient 31, and Patient 59). This failure had the potential to result in unaccounted controlled | A 489 | | |

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substances losses and compromise patient care. (Refer to A0494).

B. Develop policies and procedures for the accurate reconciliation of diluted controlled drug waste, which included refractometer (a refractometer works using the principle of light refraction through liquids. As light passes from air into a liquid it slows down, thus a known sample of each drug (index) is used to compare with the returned waste) use for 311 hospital patients. This failure had the potential to result in diversion of controlled drugs, which could affect patient care outcome. (Refer to A0494).

C. Develop a system for closing out and following up on controlled drug losses for 311 hospital patients. This failure had the potential to result in hospital staff diverting controlled drugs. (Refer to A0494).

D. Develop and implement a controlled drug diversion system, which would readily detect and identify diversion throughout the hospital for 311 hospital patients. This failure had the potential to result in hospital staff abusing controlled drugs. (Refer to A0494).

3. The hospital failed to ensure room temperatures were monitored and recorded in two out of two medication storage areas in the Emergency Department (ED- Zone 1 and Zone 2) in accordance with state laws. This failure had the potential for unsafe medication storage and administer medications with reduce potency. (Refer to A0500).

4. The hospital failed to provide pharmaceutical

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services, including procedures that assured a registered pharmacist provide safe supervision and oversight for intravenous or IV (into vein) medication services to meet the safety standards on sterile (germ-free) medication compounding (mixing medications) for 311 hospital patients. These failures had the potential of providing unsafe sterile medications for use by hospital patients. (Refer to A0501).

5. The hospital failed to ensure Intravenous (IV-inject into the vein) medication Propofol (sedation medication) was secured to prevent unauthorized access for one of one patient (Patient 1). This failure resulted in increased tampering and diversion of IV Propofol by unauthorized personnel, as well as compromised the integrity and safety of the IV medication administration for Patient 1. (Refer to A0502).

6. The hospital failed to ensure controlled medications, zolpidem (a sedative sleep medication) for one of 72 sampled patients (Patient 72) and multiple boxes of lorazepam (sedation medication) were secured in a locked container during inspection of the main pharmacy. These failures had the potential to result in unauthorized persons to have access to controlled substances or divert drug (the unlawful channeling of regulated medication from legal sources to the illicit marketplace).
(Refer to A503).

7. The hospital failed to remove expired medications (medications that may not have full effect when used) and accurately track Beyond-Use-Date (or BUD -the date after which a dispensed product should no longer be used by a patient) of medications from active stock in the

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| A 489 | Continued From page 231<br>main pharmacy for 311 hospital patients. This failure had the potential for contaminated or ineffective medication use in the hospital. (Refer to A0505).<br><br>8. The hospital failed to implement a system, which required ordered medications to be reviewed, reordered, and stopped in accordance with the drug manufacturer's specification and standards of practice for one of one sampled patient (Patient 68). This failure had the potential to result in a patient receiving less than optimal medical care and affect patient safety. (Refer to A0507).<br><br>The cumulative effects of these systemic failures had the potential for unsafe pharmaceutical services and potential drug diversion in the hospital. | A 489 | | |
| A 491 | PHARMACY ADMINISTRATION<br>CFR(s): 482.25(a)<br><br>[§482.25 Condition of Participation: Pharmaceutical Services<br>.....The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.]<br><br>§482.25(a) Standard: Pharmacy Management and Administration<br>The pharmacy or drug storage area must be administered in accordance with accepted professional principles.<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to ensure performance evaluation | A 491 | | |

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(or performance review, a formal assessment in which a manager evaluates an employee's work performance, identifies strengths and weaknesses, offers feedback, and sets goals for future performance) for two of two pharmacy technicians (RXT 1 and RXT 2), who worked under the supervision of a pharmacist to accurately prepare and distribute medications, were reviewed and signed by a pharmacist in leadership position. This failure had the potential for unsafe oversight of pharmacy technician's performance when it was not communicated and evaluated by a licensed pharmacist in leadership position.

Findings:

During a review of RXT 1s "Personnel File", RXT 1s electronic performance evaluation dated 9/15/20 was reviewed. The performance evaluation did not indicate it was signed by a licensed pharmacist in management position.

During a review of RXT 2s "Personnel File", RXT 2s electronic performance evaluation dated 3/19/21 was reviewed. The performance evaluation did not indicate it was signed by a licensed pharmacist in management position.

During an interview on 3/31/21, at 1:24 PM, with the Assistant Director of Pharmacy Services(ADPS), ADPS stated there was no requirement for pharmacy manager to sign the performance review for technicians. ADPS added that the Pharmacy Technician Manager (PTM), who was not a pharmacist, provided the training and signed the performance review. In addition, ADPS stated, the electronic system for performance review allowed one signature from

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| A 491 | Continued From page 233<br>the pharmacy and did not allow for a second signature by the licensed pharmacy manager.<br><br>During an interview on 4/1/21, at 6:35 PM, with ADPS, ADPS stated, "We are going to do something about the process of pharmacist evaluating pharmacy technician performance evaluation."<br><br>During a review of the "Job Description for the Director of Pharmacy," dated 6/24/20, the job description indicated, "The Director of Pharmacy is responsible for the oversight of pharmacy operation. . . This includes drug distribution, personnel, and quality of operation. . .Job Responsibilities: The Director of Pharmacy is responsible for all personnel actions in the department including employment, evaluation. . ."<br><br>During a review of the "Job Description for the Assistant Director of Pharmacy" dated 6/23/20, the job description indicated, "Job Responsibilities: Oversee actions, performance and productivity of the staff to assure meeting job description functions, vision, and direction of the pharmacy department." | A 491 | | |
| A 494 | PHARMACY DRUG RECORDS<br>CFR(s): 482.25(a)(3)<br><br>Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to:<br><br>A. Implement a system to ensure that all controlled drug waste had been accurately | A 494 | | |

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reconciled and accounted for five of eight patients (Patient 26, Patient 27, Patient 28, Patient 31, and Patient 59), records reviewed. This failure had the potential to result in unaccounted controlled substances losses and compromise patient care.
B. Develop policies and procedures for the accurate reconciliation of diluted controlled drug waste, which included the use of a drug refractometer (a device that uses the principle of light refraction through liquids. As light passes from air into a liquid it slows down, thus a known sample of each drug (index) is used to compare with the returned waste), for one of one physician (MD) 1's audit records. This failure had the potential to result in diversion of controlled drugs, which could affect patient care,
C. Develop a system for closing out and following up on controlled drug losses for 311 hospital patients. This failure had the potential to result in hospital staff diverting controlled drugs.
D. Develop and implement a controlled drug diversion system, which would readily detect and identify diversion throughout the hospital for 311 hospital patients. This failure had the potential to result in hospital staff abusing controlled drugs.

Findings:

A. During a concurrent interview and record review, on 3/22/21, at 10:30 AM, with the Director of Pharmacy Services (DPS), the "Controlled Drug Discrepancies/Losses Log" was reviewed. The log indicated several controlled drug discrepancies/losses remained unresolved, as emails between the Pharmacy staff had not reached the appropriate hospital staff responsible for resolving the controlled drug discrepancies for Patient 26, Patient 27, Patient 59, Patient 28, and

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Patient 31. The following controlled drug discrepancies remained unresolved for several months or longer:

1. For Patient 26, On 1/6/20, at 6:22 AM, one prescribing provider removed Fentanyl (a controlled drug) 250 mcg (micrograms - unit of measurement) / 5 ml (milliliters) vial from the Operating Room (OR) Automated Drug Dispensing device (ADD). The administration of this dose or the waste of this medication was never recorded in the patient's medical record for more than one year. DPS confirmed the findings.

2. For patient 27, On 1/6/20, at 7:44 PM, one prescribing provider removed Fentanyl 250 mcg/5 ml vial from the OR Automated Drug Dispensing device. The administration of this dose or the waste of this medication was never recorded in the patient's medical record for more than one year. DPS confirmed the findings.

3. For patient 59, On 11/15/20, at 7:45 AM, one prescribing provider removed Fentanyl 100 mcg /2 ml vial from the OR Automated Drug Dispensing device. The administration of this dose or the waste of this medication was never recorded in the patient's medical record for more than 4 months. DPS confirmed the findings.

4. For patient 28, On 11/18/20, at 11:40 AM, one prescribing provider removed) Meperidine (a controlled drug) 50 mg/ml vial from the OR Automated Drug Dispensing device. The administration of this dose or the waste of this medication was never recorded in the patient's medical record for more than 4 months. DPS confirmed the findings.

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5. For patient 31, On 7/6/20, at 4:25 PM, one prescribing provider removed Fentanyl 100 mcg /2 ml vial and Midazolam (a controlled drug) 2 mg/ml vial from the OR Automated Drug Dispensing device. The administration of these doses or the waste of these medications were never recorded in the patient's medical record for more than 7 months. DPS confirmed the findings.

During a review of the hospital's policy and procedure (P&P) titled, "Pyxis Anesthesia System," dated 2/17/21, the P&P indicated, "Discrepancy Documentation and Resolution. . .Medication - Controlled Substances 1. Accuracy of controlled substances inventory and timely resolution of discrepancies are critical components of medication security. Timely resolution of controlled substances discrepancies is a matter of paramount importance. Controlled Substances discrepancies must be resolved as soon as possible, the timeframe for discrepancy resolution should be no later than 24 hours from the time of discovery.

B. During a concurrent interview and record review, on 3/22/21, at 10:50 AM, with DPS, the hospital's weekly refractory audits for controlled drugs were reviewed. The refractory audits for controlled drugs, dated 3/17/20, 3/25/20, 4/1/20, 4/7/20, 4/21/20, and between 5/19/20 and 1/2/21 indicated, "Hydromorphone (Dilaudid) 2 mg/ml and Midazolam (Versed) 5 mg/ml, had been diluted by some providers for cases in the OR. DPS stated, when the waste from the diluted Dilaudid and Versed had been returned back to the Pharmacy, the Pharmacy used a Refractometer If the refractory index for the returned drug waste is different than the known index for the actual drug, then the pharmacy

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knows that this drug waste, has been diluted and the real controlled drug could have been diverted by the provider, from the hospital. During the hospital's weekly refractometry audits, the hospital failed to follow up on these waste discrepancies. The following were noted in the weekly controlled drug waste audits using the Pharmacy's drug refractometer:

1) On 3/17/20, MD 1 returned diluted Midazolam (Versed) 5 mg/ml waste to the Pyxis. The Pharmacy's refractometer was unable to determine that this returned controlled drug waste was actually Midazolam. DPS verified the findings.

2) On 3/25/20, MD 1 returned diluted Midazolam (Versed) 5 mg/ml waste to the Pyxis. The Pharmacy's refractometer was unable to determine that this controlled drug waste was actually Midazolam. DPS verified the findings.

3) On 4/1/20, MD 1 returned diluted Fentanyl (Sublimaze) 50 mcg/ml waste to the Pyxis. The Pharmacy's refractometer was unable to determine that this controlled drug waste was actually Fentanyl. DPS verified the findings.

4) On 4/7/20, MD 1 returned diluted Midazolam (Versed) 5 mg/ml waste to the Pyxis. The Pharmacy's refractometer was unable to determine that this controlled drug waste was actually Midazolam. DPS verified the findings.

5) On 4/21/20, MD 1 returned diluted Midazolam (Versed) 5 mg/ml waste to the Pyxis. The Pharmacy's refractometer was unable to determine that this controlled drug waste was actually Midazolam. DPS verified the findings.

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6) Between 5/19/20 and 1/2/21, MD 1 had seven more returns of Midazolam waste to the Pyxis, which could not be analyzed by the Pharmacy's refractometer as "real" controlled drug waste. DPS verified the findings.

7) Between 5/19/2020 and 1/2/21, MD 1 had 2 more returns of Fentanyl waste to the Pyxis, which could not be analyzed by the Pharmacy's refractometer as "real" controlled drug waste. DPS verified the findings.

During a review of the hospital's policy and procedure (P&P) titled, "Drug Procurement/Inventory Control," dated 9/19/18, the P&P indicated, "A. The pharmacy department is responsible for the acquisition of pharmaceuticals for the hospital. . . for quality, quantity, and source of supply of all drugs used in the hospital. Special consideration is given to the current ASHP (American Society of Health Systems Pharmacists) Guidelines for selecting pharmaceutical manufacturers and suppliers."

During a review of the hospital's policy and procedure (P&P) titled, " Standard and Services: Department of Pharmacy, dated 9/19/18, the P&P indicated, ". . .The Pharmacy will operate 24 hours. . .It shall adhere to all applicable laws and regulations, licensure, and strive to achieve the professional standards of practice outlined by nationally recognized organizations with expertise in medication use systems (e.g. American Society of Health Systems Pharmacists,. . .).

During a review of ASHP's statement on the "Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance," the

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statement indicated, "Prevention: Pharmacist should be involved in substance abuse prevention by performing the following activities: . . 6. Working with medical laboratories to (a) identify substances of abuse. . .(b) establish proper specimen collection procedures based on knowledge of the pharmacokinetic properties of abused substances, and (c) select proper laboratory tests to detect the suspected substances of abuse and to detect tampering of samples. . ." The hospital never used or consulted with a medical laboratory to properly test their diluted waste as outlined in ASHP's standards of practice.

C. During a review of the "List of Controlled Drug Diversion Events" which occurred in the hospital, the list of controlled drug diversion events indicated, "On 1/8/21, a controlled drug bottle (30 ml) of Oxycodone 20 mg/ml had been sent to the hospital by the drug manufacturer with a shortage of 19 milliliters (ml) missing from the bottle. The hospital contacted the drug manufacturer and the local police department. A case number was assigned by the drug manufacturer for the missing Oxycodone. From 1/8/21 to 3/22/21 (74 days) the facility had not followed up with the drug manufacturer to determine if the missing controlled drug would be replaced or if the hospital would be credited for the drug loss.

D. During an interview on 3/23/21, at 11:55 AM, with the Director of Medical Staff Services (DMSS), DMSS was asked about a case where MD 1 had been diverting controlled drugs from the hospital. DMSS stated the first Hospital "Midas Report" (a written report of concern), regarding MD 1's possible controlled substance abuse went back to 7/22/20, so the hospital was

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aware of a previous concern regarding MD 1. The Operating Room (OR) staff had received an educational training on controlled drug diversion on 1/7/21. As a result of this training, new concerns regarding MD 1 resurfaced for at least one of the OR practitioners regarding controlled drug diversion. On 1/11/21, (the second "Midas Report") had been completed by a practitioner and submitted to MD 2. On 1/13/21 MD 2 and MD 4 interviewed MD 1. An additional meeting on 1/20/21 took place with MD 1 being present with DMSS and DPS. MD 1 shared with DMSS and DPS. MD 1 had come forward to self-report he had been diverting controlled narcotic medications from the hospital drug supply, while working at the hospital between 5/2020 to 1/2021 (over an 8 month period). MD 1 indicated he had been documenting in each patient's chart he had used the total amount of controlled drug, which had been taken from the hospital's Automated Drug Delivery Device (Pyxis is an automated drug storage cabinet), similar to an ATM (Automated Teller Machine). MD 1 indicated that he wanted to share how he had been able to divert his controlled drugs without being detected by the hospital's-controlled drug diversion system. MD 1 also wanted the hospital to know, so that the hospital could put an effective system into place, which could prevent this type of diversion from happening again, in the future at this hospital. MD 1 indicated that his method of diverting these controlled medications was that he would set aside 1/3 of each patient's controlled drug for later personal consumption in order to satisfy his addiction. The hospital's current drug diversion system never picked up on MD 1's diversion technique, which this physician had employed."

During an interview on 4/1/21, at 7AM, with the

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hospital's Chief Executive Officer (CEO) and DPS, DPS stated the hospital still has not develop or implemented a controlled drug diversion system, which would have prevented or alerted the hospital to the type of diversion technique, which MD 1 had been using and had been undetected for at least 8 months. The hospital's administrative staff and the pharmacy administrative staff acknowledged the hospital has failed to develop a system to effectively account for all controlled drug usage and it has failed to develop a system for tracking and trending controlled drug losses for future diversion.

During an interview on 4/1/21, at 6:15 PM, with the Assistant Director of Pharmacy Services (ADPS), ADPS confirmed the hospital did not have systems in place to monitor the losses and trends for their controlled substance use and loss.

During a review of the hospital's policy and procedure (P&P) titled, "Reporting Requirements for Drug Diversion Illegal Substance Abuse or Controlled Substance Abuse," dated 8/24/20, the P&P indicated, "4. Drug diversion will be considered confirmed if after investigation there is: a. An admission of guilt by the person suspected; b. Refusal to consent to drug testing or to authorize a release of the test results per Human Resources Policy HR.200 Drugs and Alcohol by the person suspected; c. Sufficient evidence of drug diversion to terminate the person suspected and all appeals to that termination have been exhausted per Human Resources Policy HR.218 NOTIFICATION REQUIREMENTS, PREDETERMINATION PROCESS AND APPEAL PROCESS FOR

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| A 494 | Continued From page 242<br>INVOLUNTARY TERMINATION, SUSPENSION WITHOUT PAY FOR MORE THAN FIVE DAYS AND DEMOTION. . ."<br><br>The hospital has not taken any personnel action with MD 1. | A 494 | | |
| A 500 | DELIVERY OF DRUGS<br>CFR(s): 482.25(b)<br><br>§482.25(b) Standard: Delivery of Services<br><br>In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.<br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to ensure room temperatures were monitored and recorded in two out of two medication storage areas in the Emergency Department's (ED, a unit is hospital that treated medical emergencies) Zone 1 and Zone 2 in accordance with state laws. This failure had the potential for unsafe medication storage and administer medications with reduced potency.<br><br>Findings:<br><br>During an observation on 3/25/21, at 12:07 PM, in the ED Zone 2, the locked medication room had multiple towers of Automated Dispensing Cabinets (ADC- a computerized drug storage device that allows drugs to be stored, tracked, and dispensed near the point of care) and a refrigerator for medication storage. Both the ED Nurse Manager (EDNM) and the Director of | A 500 | | |

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Emergency Services (DES) were unable to locate a thermostat that monitored the medication room.

During an interview on 3/25/21, at 12:21 PM, with EDNM, EDNM stated, pharmacy tracked and kept a daily log of the temperature readings in all medication rooms. EDNM stated the entire department was ventilated through a central air conditioning system.

During a review of the temperature-monitoring log titled, "Temperature Log for Refrigerated Vaccines," dated 3/21, the temperature log indicated, refrigerator temperature monitoring for medication refrigerator in Zone 1 and medication refrigerator in Zone 2, were documented twice a day. The temperature log did not indicate monitoring of the medication room temperature.

During an interview on 3/31/21, at 12:23 PM, with the Assistant Director of Pharmacy Services (ADPS), ADPS stated her staff did not record or monitor room temperatures in medication storage areas, including medication rooms in the ED. ADPS added, no one in the pharmacy or the ED expressed any need for medication room temperature monitoring.

During a review of the hospital's policy and procedure (P&P) titled, "Storage and Security of Medications," dated 2/7/21, the P&P indicated, "All medications are stored in a manner such that. . .medication integrity is maintained. . .and drugs shall be stored at appropriate temperatures."

During a review of the "American Society of Health-System Pharmacy (ASHP) Guidelines on Minimum Standard for Pharmacies in Hospitals," last accessed on 4/5/21, the guidelines indicated,

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| A 500 | Continued From page 244<br>"Medication Storage and Preparation Areas ... shall be suitable facilities to enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital." | A 500 | | |
| A 501 | PHARMACIST SUPERVISION OF SERVICES<br>CFR(s): 482.25(b)(1)<br><br>§482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.<br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to provide pharmaceutical services, including procedures that assured a registered pharmacist provide safe supervision and oversight for intravenous or IV (into vein) medication services to meet the safety standards on sterile (germ-free) medication compounding (mixing medications) for a census of 311 hospital patients as evidenced by:<br><br>1. The Pharmacy Technician (RXT 1) did not change gloves in between medication preparation and restocking of unsterile products. This had the potential to result in cross-contamination.<br><br>2. The Direct Compounding Area (DCA- a critical area within a compounding hood [a sterile surface where clean air constantly flows to help maintain a germ-free medication preparation] where sterile medications are prepared in a filtered air [air without contaminants]) was blocked with products or supplies. This had the potential to result in | A 501 | | |

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exposure of the steriled medications to contaminants.

3. The Pharmacy Technician (RXT 1) did not change the disposable needle after removing IV fluids from a sterile solution and reused the same needle for the next IV admixture. This had the potential to result result in cross-contamination of IV admixture.

4. Safety check for clarity or presence of a particulate matter (floating small particles or cloudiness of the sterile fluid) was not done on a finished IV product after compounding. This had the potential to result in unsafe compounding practice.

5. One Environmental Services (a department in the hospital responsible for cleaning and housekeeping) Staff (EVS 1) who had no training in cleaning the specialized pharmacy clean room provided cleaning services. This had the potential of providing unsafe sterile medications for use of 311 hospital patients.

Findings:

1. During a concurrent observation and interview, on 3/22/21, between 9:30 AM to 10:30 AM, in the pharmacy clean room (a room where intravenous medications were prepared in a germ-free environment), RXT 1 did not change her sterile gloves when leaving the clean room, preparing multiple medications, and restocking the unsterile medication products. RXT 1 was observed using alcohol (antiseptic) spray to clean her gloves in between tasks. RXT 1 did not respond when asked about the frequency of glove change but immediately removed and changed her gloves.

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There was no pharmacist stationed in the clean room to supervise or monitor aseptic technique (refers to practices performed to prevent the spread of germs and maintain a sterile environment) practices during compounding activities (the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of a patient).

During an interview on 3/22/21, at 10:21 AM, with RXT 1, RXT 1 stated, the sterile products she prepared were remotely reviewed and approved by the pharmacist using a computer technology called DoseEdge (a computerized system using imaging check system to approve IV preparation remotely by a pharmacist).

During an interview on 3/26/21 at 4:08 PM, with the Assistant Director of Pharmacy (ADPS), ADPS stated the observation and assessments of pharmacy staff work practices inside the clean room were conducted during annual competency (a validation of knowledge and skills specific to employee role and job responsibility to make sure the staff can perform the job proficiently.) ADPS added, for ongoing monitoring of the daily work activity inside the clean room, pharmacists needed to do more observation and provide more oversight. ADPS stated, they were in the process of hiring a pharmacist to supervise the IV clean room operation.

During a review of the pharmacy's Policy and Procedure (P&P), titled, "Infection Control," dated 2/20/20, the P&P indicated, "Pharmacy personnel shall follow established procedures to reduce the risk of introducing microbial contamination into the distribution system. . . Strict aseptic (germ-free) technique will be maintained when

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preparing sterile (germ-free) preparation. Supportive personnel are supervised by a Registered Pharmacist for strict adherence to aseptic technique."

2. During an observation on 3/22/21, at 10:12 AM, in the pharmacy compounding area, the Direct Compounding Area (DCA) was blocked by a box of supplies containing needles, alcohol pads, and multiple vials of medications. The DCA area protected the compounded IV medication from being contaminated by uninterrupted clean air using the HEPA filter (High Efficiency Particulate Air-filtered air that traps harmful particles).

During an interview on 3/22/21, at 10:12 AM, with RXT 1, RXT 1 stated the supplies and vials of medications inside the compounding hood were used frequently throughout the day. RXT 1 could not explain if those items could affect the germ-free environment maintained in the DCA.

3. During an observation on 3/22/21, at 10:14 AM, in the pharmacy's clean room workflow, with RXT 1, RXT 1 attached a disposable (one time use) needle to a tubing connected to a pump that removed fluid from a sterile IV solution of Normal Saline (a mixture of germ-free salt and water used for mixing IV medications.) RXT 1 was observed using the same needle to remove excess fluid from the next IV solution of Normal Saline for another medication compounding.

During an interview on 3/22/21, at 10:15 AM, with RXT 1, RXT 1 stated that it was not required to change the disposable needle for the same solution type. RXT 1 added, she would remember to change the needle with a different IV fluid.

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During a review of the pharmacy's Policy and Procedure (P&P), titled, "Infection Control," dated 2/20/20, the P&P indicated, "Pharmacy personnel shall follow established procedures to reduce the risk of introducing microbial contamination into the distribution system. . . Strict aseptic (germ-free) technique will be maintained when preparing sterile (germ-free) preparation. Supportive personnel are supervised by a Registered Pharmacist for strict adherence to aseptic technique."

4. During an observation on 3/22/21, at 10:30 AM, in the pharmacy's clean room, compounding practices were observed. RXT 1 prepared the IV medication in the clean room and the pharmacist checked the preparation document via DoseEdge imaging (picture taking) technology remotely. The final product was picked up by another pharmacy technician through a window connected outside of the clean room for final step of relabeling and dispensing.

During an interview on 3/23/21 at 10:58 AM, with Registered Pharmacist Inpatient (RPHINPT), RPHINPT stated the pharmacy technician would scan the IV bag in the computer system to get the second label that had product's expiration date or beyond use date (BUD)- the date the product should not be used) and dispensing time. RPHINPT added that pharmacy technicians are responsible to check for particulate matter or clarity of the IV solution products. RPHINPT acknowledged that pharmacist could not safely detect particulate matter inside an IV solution bag through the imaging software the hospital was using.

During an observation on 3/23/21, at 11:40 AM, in

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the main pharmacy, Pharmacy Technician Inpatient (RXTIP 1) processed the labeling and dispensing of an IV medication. RXTIP 1 was observed picking up an IV product from the pharmacy's clean room window; he then scanned it into the computer system to get the final label for dispensing. RXTIP 1 did not inspect for clarity or possible particles inside the IV solution. The prescription label covered one side of the IV bag and RXTIP 1 did not turn the bag around to look for cloudiness or inspect for presence of particulate matter.

During an interview on 3/24/21, at 9:51 AM, with Registered Clinical Pharmacist (RPHICU), RPHICU stated she often checked the IV product preparation via DoseEdge imaging technology in her computer remotely. RPHICU acknowledged it was difficult to see small particulate matter inside an IV solution bag after it had been compounded, using the computer imaging system remotely.

During an interview on 3/26/21 at 03:12 PM, with ADPS, ADPS stated, it is the technician's responsibility to check and detect particulate matter or cloudiness of the compounded IV products. She stated they needed to do more with observation and oversight of the daily work activity. ADPS added the hospital was in the process of hiring a pharmacist with focused responsibility on sterile compounding area.

During a review of the hospital's policy and procedure (P&P) titled, "Compounded Sterile Preparation Service," dated 2/21/20, the P&P indicated, "The pharmacy department will provide Compounded Sterile Preparation (CSP - medications prepared from ingredients in sterile environment) services. Patients will receive CSPs

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prepared aseptically, which have been checked by the pharmacist for appropriateness . . . The final labeled preparation. . . are left for the pharmacist for end product verification. . .The completed end products are visually inspected for clarity, color change, integrity of container, and coring of stopper (when a small piece of a vial's rubber stopper breaks off and contaminates the contents of a sterile solution). . . If the pharmacist approves the compounded sterile preparation for use, the pharmacist initials the label or accepts the dose in the IV Workflow Management System (the hospital's computer and imaging check system)."

During a review of the hospital's policy and procedure (P&P) titled, "Quality Assurance Program: Compounding Medications," dated 8/21/20, the P&P indicated, "Prior to dispensing for patient use, every dose is inspected, and initialed, or approved by a pharmacist to assure accurate preparation and labeling. Compounded sterile preparations . . . shall be visually examined for expected appearance and physical integrity (e.g. the presence of particulate matter) and not administered or dispensed when such matter is observed."

During a review of the Institute for Safe Medication Practices Guidelines (ISMP-a leading medication and patient safety organization), titled, "Guidelines for Safe Preparation of Compounded Sterile Preparation," accessed on 4/5/21, the Guidelines indicated, "Standard Operating Procedures (SOP-same as policy and procedure) for compounding and checking all CSPs are utilized and are sufficiently detailed to prevent process variation in practice among staff. When technology is in use to assist with sterile

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compounding, organizations have SOPs that ensure that the final check of the preparation has been completed prior to dispensing by a pharmacist possessing training and experience with the technology."

5. During a concurrent observation and interview, on 3/22/21, at 11:59 AM, with the Pharmacy Manager (RXM), in the main pharmacy clean room area, a cleaning log was posted outside of the door. RXM stated the Environmental Services (or EVS- a department in the hospital responsible for cleaning and sanitizing) staff documented their cleaning activity on the log on a daily basis. Additionally, there was a list of EVS personnel with specialized training authorized to remove trash, sweep the surfaces, and sanitize the clean room. RXM verified the findings and stated the pharmacy staff was to confirm eligibility of the EVS staff when they entered the main pharmacy to service the clean room.

During a review of an EVS document titled, "Support Personnel Clean Room Training List," undated, the document indicated, "EVS staff 1 (EVS 1) who performed the cleaning tasks on 3/13/21, 3/14/21,3/2021, and 3/21/21 was not on the eligible list of staff allowed to clean the pharmacy clean room.

During an interview on 3/26/21 at 3:38 PM, with ADPS, ADPS stated the EVS management was responsible for assuring the trained EVS staff were scheduled for cleaning and sanitizing pharmacy's clean room.

During an interview on 3/30/21, at 8:45 AM, with EVS Manager (EVSM), EVSM stated they could not locate any training document on pharmacy's

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| A 501 | Continued From page 252<br>clean room tasks for EVS 1. EVSM stated EVS 1 had one week of shadowing with another trained EVS staff member. EVSM was not aware of a weekly and monthly cleaning requirements for pharmacy's clean room. EVSM acknowledged EVS cleaning log did not include the length of time or a time-stamp for the cleaning process.<br><br>During a review of the EVS staff training document titled, "Pharmacy Clean Room Suite Evaluation," undated, the document indicated, "The last step in cleaning of the compounding room requires that EVS staff document cleaning on the log sheet, including time, date and signatures." | A 501 | | |
| A 502 | SECURE STORAGE<br>CFR(s): 482.25(b)(2)(i)<br><br>§482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area,<br>and locked when appropriate.<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the facility failed to ensure Intravenous (IV- inject into the vein) medication Propofol (sedation medication) was secured to prevent unauthorized access. This failure had the potential to result in increased tampering and diversion of IV Propofol by unauthorized personnel, as well as compromised the integrity and safety of the IV medication administration for Patient 1.<br><br>Findings:<br><br>During a review of Patient 1's "Emergency Documentation" (ED notes), dated 12/21/20, the "ED notes" indicated, Patient 1 was a 58-year-old male admitted to the hospital on 12/21/20. | A 502 | | |

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| A 502 | Continued From page 253<br><br>During a review of Patient 1's "Physician's Orders" dated 12/21/20, at 10:01 PM, the Physician Orders indicated, "Propofol additive 2,000 mg (milligrams- unit of measure). . .5 mcg (micrograms-unit of measure)/ kg (kilograms-unit of measure)/min (minute)]. . .Adjust by 5-10 mcg/kg/min every 5 min. . .Goal RASS [Richmond Agitation-Sedation Scale- a medical scale used to measure the agitation or sedation level of a person] score of -2[light sedation] to 0 [alert and calm]. . ."<br><br>During a review of Patient 1's "Medication Administration Record (MAR) Summary", dated 12/21/20, the MAR Summary indicated, " Propofol was administered at 5 mcg/kg/min at 10:07 p.m., and Propofol was discontinued at 10:09 PM."<br><br>During a telephone interview on 1/29/21 at 5:24 PM, with Registered Nurse (RN) 1, RN 1 acknowledged she initiated Propofol administration using a 100 ml (milliliters- unit of measure) Propofol bottle and stopped it two minutes later. RN 1 stated she paused Propofol administration and left the bottle of Propofol hanging on the pole in Patient 1's room as she went in and out of the patient's room. On 12/22/21, at 1:50 AM, RN 1 stated , "I noticed ¾ (approximately 75 ml) of the 100 ml Propofol was missing and notified nurse in charge and filed a police report. RN 1 stated, "I thought it spilled, I looked on the floor, didn't see anything, the patient was passing away. I stepped out. . . I spoke with another co-worker [RN 3] and it got brought up that the scribe [SC- person who takes notes for the physician 1] was acting different and was not himself. . . [SC 1] was found in locked restroom unresponsive with white substance" | A 502 | | |

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During a review of the police report filed by the hospital, the police report, dated 1/21/21, indicated, a healthcare worker died from an overdose on Propofol emulsion that he had diverted from an infusion that was intended for a patient.

During an interview on 2/3/21 at 1:50 PM, with MD 7, MD 7 stated scribes typically stayed at their computer station, but were not under direct supervision the entire time. MD 7 acknowledged SC 1 was his scribe on 12/21/2020. MD 7 stated he did not see SC 1 for 2 hours, and SC 1 did not respond when MD 7 paged him. MD stated staff found SC 1 with a syringe in the restroom and SC 1 was already in cardiac arrest (heart stops working) when security unlocked the restroom.

During a review of the contracted company's document, "Job Description for Scribes", revised December 2017, the "Job Description for Scribes" indicated, "A scribe is an unlicensed person who enters information into the electronic medical record (EMR) or chart at the direction of a physician or practitioner. A scribe functions under the direct supervision of the provider."

During an interview on 2/3/21, at 3:04 PM, with Emergency Department Nurse Manager (EDNM), EDNM acknowledged SC 1 was not authorized to be in a patient's room without a physician.

During an interview on 3/22/21 at 6:38 PM, with RN 2 and EDMN, RN 2 stated SC 1 was found unresponsive in one of the ED restrooms in the early morning of 12/22/21 with two syringes about 30 ml each, one full with milky substance and one empty next to his body. When asked what

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was in the syringes, EDMN acknowledged it was most likely Propofol. EDMN stated, "If you have been in critical care, you know what Propofol look like." RN 2 stated if Propofol was discontinued, a nurse should have taken down the medication and wasted it in the medication waste bin.

During an interview on 3/22/21, at 7:45 PM, with EDMN and RN 3, RN 3 acknowledged she was present in the early morning of 12/22/2020, when SC 1 was found unresponsive in one of the ED restrooms. RN 3 stated, "We opened door to restroom and he [SC 1] was dead, on the floor but kind of slugged on the wall. I saw a syringe, I think there was medication there ... It was a traumatic event. . ." RN 3 acknowledged it was not standard for IV medication to be hanging on a pole in a patient's room when the medication was not being administered to a patient. EDMN acknowledged once RN 1 stopped administering Propofol to Patient 1, she should have removed Propofol from the patient's room and properly wasted the Propofol.

During an interview on 3/22/21, at 9:53 PM, with Resident (physician in training) 2, Resident 2 acknowledged he was working in the ED, on the night of 12/21/20. Resident 2 stated if he had seen Propofol hanging on a pole in the patient's room after he had placed a discontinuation order for Propofol, he would advise the patient's nurse to take it out of the room to prevent the Propofol from being used incorrectly.

During a follow up interview and record review, on 3/25/21, at 9:31 PM, with RN 1, Patient 1's medical records, dated 12/21/20, were reviewed. Patient 1's medical records indicated, on 12/21/20, there were no physician's orders to hold

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or discontinue Patient 1's Propofol. RN 1 acknowledged she did not get a physician's order to hold or discontinue Patient 1's Propofol and did not ask the physician what to do with Patient 1's Propofol. RN 1 stated she stopped administration of Propofol for Patient 1 because she was unable to get a blood pressure for Patient 1. RN 1 stated she left the Propofol for Patient 1 on the IV pole after she stopped the infusion because she was busy trying to keep Patient 1 alive.

During a review of "DailyMed," a nationally recognized drug reference, regarding Propofol drug dependence and abuse, Propofol drug manufacturer states, "There are reports of the abuse of propofol for recreational and other improper purposes, which have resulted in fatalities and other injuries. Instances of self-administration of propofol by healthcare professionals have also been reported, which have resulted in fatalities and other injuries. Inventories of propofol should be stored and managed to prevent the risk of diversion, including restriction of access and accounting procedures as appropriate to the clinical setting."

During a review of the hospital's policy and procedure (P&P) titled, "Medication Administration," dated 6/19/19, the P&P indicated, "I.A.14. HOLD Orders are intended to interrupt therapy for a short period of time due to changes in the patient's condition or pending procedures. Orders placed on HOLD by the prescriber without a specified duration or number of doses will be discontinued unless further orders are received to resume, discontinue, or modify the medication."

During an interview on 3/26/21, at 10:18 AM, with

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Security Officer (SO), SO stated he was working at Zone 2 in the ED on 12/21/20, when SC 1 overdosed. SO acknowledged he documented an incident report regarding the night SC 1 overdosed. SO stated, "I received a call to go to Zone 1[in the ED] bathroom because it was closed for some time . . .When I opened the door, the scribe [SC 1] was on the floor . . .door to bathroom opens outward, he was directly in front of me in the corner of the restroom in front of the toilet. . .it looked like he had fallen from the toilet straight into the curve of the bathroom. He was kind of curved towards the door. . .he was unresponsive, there was a little bit of blood near his head, he was pale. . .the staff members behind me immediately recognize it was a code blue [medical emergency] situation and started yelling for people to help and I got out of way. . .I reviewed the video when I returned for my shift at 1900 [7 PM] 12/22/20 regarding [SC 1] entering Room 19 at 00:32. He left Room 19 and entered bathroom at 00:34. I reviewed footage until I saw him enter that room. . .cannot recall when started reviewing Zone 1 camera. I did not review other cameras because they do not have access to the bathroom. . .[RN 3] informed security during debriefing that she believed [SC 1] gained access to the drug by filling two syringes from a Propofol container that was meant to be given to a patient in Room 19 of the ED and went inside of the Zone 1 restroom when he ultimately injected himself with the drug ..."

During a review of the hospital's "Incident Report", dated 12/22/20, at 12:34 AM to 12/22/20 2:33 AM, " the "Incident Report" indicated, "On December 22, 2020 at approximately 0209 hours, I was in Zone 4 of the Emergency Department (ED) when I received a call for service via radio to

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assist [. . .] in gaining access to the Zone 1 restroom. The restroom was reportedly locked for a couple of hours and nobody would answer when staff knocked. Upon my arrival, I knocked on the door with no response. I then opened the door cautiously and witnessed employee [SC 1] down in the corner of the room with some blood around him . . . During the investigation, it was learned that staff members had found syringes with a milky substance, alcohol wipes, and blood in the staff restrooms outside of Zone 3 this night and the night prior. They had concerns that a staff member was potentially using drugs in that location . . . [RN] also informed security during our debriefing that she believed [SC 1] gained access to the drug by filling two syringes from a Propofol container that was meant to be given to a patient in Room 19 of the ED and went inside of the Zone 1 restroom where he ultimately injected himself with the drug. After video review, it was learned that [SC 1] entered Room 19 at 0032 [thirty minutes past midnight]. He left Room 19 and entered the Zone 1 restroom at 0034 hours [thirty-four minutes past midnight]."

During a concurrent interview and record review, on 3/26/2021, at 2:24 PM, with the County Coroner's Office Detective (DET), SC 1's "Complete Drug Screen Report", dated 12/23/20, and "Final Autopsy Report" dated 1/7/20, were reviewed.

The "Complete Drug Screen Report" indicated, "Specimen: Blood Sample ... Complete Drug Screen: Venlafaxine [medication for depression] detected. . .Venlafaxine= 0.32 mg/L. . . Desmethylvenlafaxine [breakdown of venlafaxine] = 0.16 g/L. . .
Blood Venlafaxine + Desmethylvenlafaxine

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Ranges (Sum [total]). . .Effective Level: Sum (0.25-0.75 mg/L). . ." DET acknowledged there was no documentation on the "Complete Drug Screen Report" dated 12/23/20 that indicated SC 1's blood specimen had been tested for Propofol. DET stated he was the detective from the Coroner's office that went out to the hospital and picked up SC 1. DET stated he did not know why Propofol was not included in the drug screen report and had included Propofol in his report. DET acknowledged he completed an incident report regarding the encounter.

During a review of the "Sheriff's Department Incident Report", dated 1/13/21, the "Sheriff's Department Incident Report" indicated, ". . . [hospital staff] told me [SC 1] was. . . assigned to the ER as a Scribe for the ER doctors. [Hospital staff] further told me when he was found, two syringes were found next to him. One of the syringes was full with Propofol and the other was empty. ER staff additionally found several syringe needles in his pants pocket. . .[Hospital staff] told me soon after [SC 1] was found a nurse reported a Propofol bottle, which had been used on a previous patient, had medication missing from it." DET stated hospital staff had already picked up the syringes and disposed of the medication when he arrived so the Coroner's office was unable to determine the contents of the syringe.

During a review of The "Final Autopsy Report" from the Coroner's Office the autopsy report indicated:
"Acute Venlafaxine [medication for depression] toxicity" ... Venlafaxine= 0.32 mg/L ... Desmethylvenlafaxine [breakdown of venlafaxine] = 0.16 g/L. . .
Blood Venlafaxine + Desmethylvenlafaxine

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Ranges (Sum [total]). . . Effective Level: Sum (0.25-0.75 mg/L). . ."
The "Final Autopsy Report" indicated, the total amount of Venlafaxine and Desmethylvenlafaxine in SC 1's blood specimen was within effective range.

During a review of SC 1's "Emergency Documentation Report", dated 12/22/20, the "ED Report" indicated, SC 1 had a home medication use history for Venlafaxine 75 mg, extended release oral capsule.

During a concurrent interview and video review on 3/30/2021 at 3:29 PM, with Security Services Manager (SSM), the "North Camera Video File 00340001 (Video 1)," dated 12/22/20 starting 12:34:04 AM to 12:37 AM, "South Camera Video File 00340002 (Video 2)," dated 12/22/2020 starting 12:34 AM to 12:37 AM, "North Camera Video File 02120001 (Video 3) dated 12/22/2020 starting 2:12 AM to 2:17 AM, and "South Camera Video File 02120002 (Video 4) dated 12/22/2020 starting 2:12 AM to 2:17 AM were reviewed.

Video 2 indicated,
12:34:32 AM, SC 1 walks in Room 19 as two hospital staff stood by door of Room 19
12:36:26 AM, SC 1 in Room 19 with doors to gray cart containing IV supplies open
12:36:35 AM, SC 1 exits Room 19
12:36:42 AM, SC 1 makes left toward Zone 1 public restroom in ED and disappears from view

Video 3 indicated,
2:12:15 AM, hospital security makes left to alcove with Zone 1 public restroom
2:12:47 AM, hospital female staff in red scrub white long sleeve shirt enters alcove

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| A 502 | Continued From page 261<br>2:12:49 AM, hospital male staff in black scrubs walks into alcove and female staff runs out<br>2:12:52 AM, hospital female staff in black scrubs run out of alcove behind female staff in red scrubs<br>2:12:57 AM, several hospital staff members run into alcove, 6th hospital staff runs in 12:13:01<br>2:14:00 AM, SC 1 is seen on gurney coming from alcove, being moved to trauma bay in hallway while staff perform chest compressions<br>2:14:21 AM, SC 1 is taken into Room 21<br><br>During a review of the hospital's policy and procedure (P&P) titled, "Medication: Security in Patient Care Areas", dated 9/23/2019, the P&P indicated, " I. H. 1. Personnel listed in I, B, 3 [Nursing personnel, Pharmacy personnel. . ] of this policy will ensure the proper security of medications at all times, including during distribution and replenishment activities."<br><br>During an interview on 4/1/2021, at 5:23 p.m. with Assistant Director of Pharmacy Services (ADPS), ADPS stated, medication like Propofol should only be accessible to authorized personnel. ADPS acknowledged SC 1 was not authorized personnel and should not have had access to Patient 1's Propofol medication. ADPS stated the facility did not handle or store Propofol as a control substance, and acknowledged the facility did not have an effective process in place for the monitoring of Propofol. | A 502 | | |
| A 503 | CONTROLLED DRUGS KEPT LOCKED<br>CFR(s): 482.25(b)(2)(ii) | A 503 | | |

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| A 503 | Continued From page 262<br>Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to ensure controlled medications were secured in a locked container during inspection of the main pharmacy for the census of 311 hospital patients when:<br><br>1. Multiple boxes of lorazepam (known as Ativan, a regulated sedative medication) were stored in an unlocked container in a refrigerator in the main pharmacy for one of one sampled patient (Patient 72).<br><br>2. One bottle of Patient 72's own medication named zolpidem (known as Ambien, a sedative sleep medication) was stored in an unlocked storage area.<br><br>These failures had the potential to result in unauthorized persons to have access to controlled substances / drug diversion (unlawful channeling of regulated medication from legal sources to the illicit marketplace).<br><br>Findings:<br><br>1. During an observation on 3/22/21, at 9:26 AM, in the pharmacy drug storage area, the main refrigerator was stocked with multiple unsecured large blue bins of lorazepam injectable (can be injected into vein or skin) medication. Each bin was labeled with a note marked as "Secured Stock" and contained boxes of lorazepam 40 mg/10mL (milligram or 'mg' and milliliter or 'ml' | A 503 | | |

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are units of measure) injectable vials.

During an interview on 3/22/21, at 11:09 AM, with Pharmacy Manager (RXM), RXM stated, the hospital was in the process of installing locked boxes inside the large refrigerator to secure the lorazepam stock. RXM added, the large quantity of the stock did not fit in the small refrigerator inside the secured narcotic room where most controlled substance medications were stored.

During a review of the hospital's policy and procedure (P&P) titled, "Storage and Security of Medication", dated 2/17/21, the P&P indicated, "Medications with significant abuse potential shall be provided an added level of control. The main supply of controlled substances shall be stored in the pharmacy CII Safe System (a computerized system that stores, tracks and monitors the controlled-substance inventory in hospital), with access limited to entry via password or biometric identification (biometric identification consists of determining the identity of a person who access the restricted area)."

During a review of the hospital's policy and procedure (P&P) titled, "Medication: Security in Patient Care Areas," dated 9/23/19, the P&P indicated, "CS (controlled substances- or regulated drugs) of any schedule that requires refrigeration should be stored in a refrigerator within a locked box secured to the inside of the refrigerator."

2. During an observation on 3/23/21, at 12:19 PM, in the main pharmacy storage space for patients own medications (POM, patients medication supply stored in the hospital pharmacy for safekeeping until they were discharged from the

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hospital), with RXM, there was an overflow of sealed bags on top of an alphabetically labeled cabinet. One sealed bag of medications belonged to Patient 72. The sealed bag was noted to contain a controlled medication named zolpidem (a sedative sleep medication). The prescription bottle for zolpidem was visible through the clear storage bag. There was no quantity specified on the outer bag of zolpidem.

During an interview on 3/23/21, at 12:25 PM, with Pharmacy Manager (RXM), RXM stated POMs were logged on a tracking binder upon patient's admit to the hospital. POM that contained narcotics were counted and sealed by nursing staff for safe storage inside pharmacy's narcotic room (a room in the hospital pharmacy where all regulated narcotics are stored). RXM added that both nursing and pharmacy staff had missed counting and securing Patient 72's own narcotic medication.

During a review of the hospital's policy and procedure (P&P) titled, "Medication: Security in Patient Care Areas," dated 9/23/19, the P&P indicated, "Patient's personal medications shall be secured by the hospital when they cannot be returned to the family/caregiver."

During a review of the hospital's policy and procedure (P&P) titled, "Medication: Patient's Personal Medication," dated 9/23/19, the P&P indicated, "All controlled medications will be counted and verified with a licensed witness. The medications are placed into a numbered patient belongings envelope. The medication will be taken to pharmacy and placed in a secured cabinet."

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| A 505 | UNUSABLE DRUGS NOT USED<br>CFR(s): 482.25(b)(3)<br><br>§482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use<br>This STANDARD is not met as evidenced by:<br>Based on observation, interview and record review, the facility failed to remove expired medications (expired means when the medication may not have full effect when used) and accurately tracked beyond-use-date (BUD is defined as the date after which a dispensed product should no longer be used by a patient) of medications from active stock in the main pharmacy for the census of 311 hospital patients when:<br><br>1. The expired packets of a liquid medication called atovaquone (known as Mepron, a medication used to treat infection) were in active stock along with multi-use medications bottles without "date open" (date open is the date when a liquid medication bottle is first opened) markings.<br>2. A compounded medication (means manually mixing and prepared medications) called folic acid liquid (folic acid is a required vitamin supplement) did not meet the compounding standards on beyond use date.<br><br>These failures had the potential for contaminated or ineffective medication use in the hospital.<br><br>Findings:<br><br>1. During an observation on 3/23/2021, at 11:06 AM, in the main pharmacy, with Pharmacy Manager (RXM), the following expired and undated open bottles (means the multi-use | A 505 | | |

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medication bottles were not dated when first opened for use) of medications were observed in the active storage area:

*Atovaquone oral suspension (liquid medication needs shaking before use - an antifungal and antiparasite medication to treat pneumocystitis pneumonia - infection of the lungs) 750 mg/5 ml (milligram or 'mg' and milliliter or 'ml' are units of measure) with expiration date of 1/2021.
*Ziduvudine oral suspension (liquid medication to treat a type of virus infection) 10mg/ml with no open date labeling.
*Furosemide (water pill) oral solution 10mg/ml with no open date labeling.
*Vitamin D supplement drops (liquid vitamin supplement) with no open date labeling.
*Vitamin E oral drop 15 IU/0.3ml ("IU" and 'ml" were unit of measure in liquid form for this vitamin supplement) with no open date labeling.
*Poly-Vi-Sol with Iron (a vitamin supplement for infant and toddler) with no open date labeling.
*Digoxin liquid (heart medication) 0.05 mg/ml with no open date labeling.
*Infant Gas Relief drop (liquid medication to reduce gas in stomach) with no open date labeling.

During an interview on 3/23/21, at 11:06 AM, with Pharmacy Technician Inpatient (RXTIP 1), RXTIP 1 acknowledged there was inconsistency on labeling the multi-use medication container for date open or beyond use date. RXT 1 stated some bottles of medication like promethazine liquid (medication used for cough), he used one year beyond use date.

During an interview on 3/23/21, at 11:36 AM, with RXM, RXM acknowledged the expired

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atovaquone oral suspension and not labeling the multi-use liquid medication container when first opened for use.

During a review of the 2014 version of United States Pharmacopeia (or USP, a drug standards enforceable in the United States by the Food and Drug Administration (FDA), which regulates safety of medication use) chapter 1191 on stability consideration in dispensing practice, last accessed on 4/7/21, indicated, "The stability as the extent to which a preparation retains, within specified limits and throughout its period of storage and use. . ." Furthermore, Pharmacists should avoid. . .conditions that could result in excessive physical deterioration or chemical decomposition of drug preparations."

During a review of "The American Society of Health-System Pharmacy (ASHP) Guidelines on "minimum Standard for Pharmacies in Hospitals" last accessed on 4/6/21, indicated "Medications shall be received, stored, and prepared under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety." The guideline further indicated, "All stocks of medications shall be inspected routinely to ensure the absence of outdated, unusable, recalled, or mislabeled products. Storage conditions that would foster medication deterioration, storage arrangements that might contribute to medication errors, and other safety issues shall be assessed, documented, and corrected."

2. During an observation on 3/23/21, at 3:55 PM, in the main pharmacy, with RXM, a bottle of compounded liquid medication was observed in

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the refrigerator active storage area. The liquid medication was labeled as "folic acid oral 1mg/mL PED Susp" (a liquid medication or suspension for use by a child or infant; "mg" and "ml" were units of measure). The amber color bottle had sticky white powder and water stain on the outer surfaces. The label on the bottle had the following preparation (the date that the product was mixed) and expiration date (date when the product is no longer safe to use): "Printed (medication prepared): 3/13/21 15:42, Expires: 05/12/21 15:42"

During an interview on 3/23/21, at 3:59 PM, with RXM, RXM stated the compounded folic acid bottle was a stock solution, which means it was used to draw up smaller doses of the medication for multiple patients. RXM added, hospital used a master formula (master formula is a document with description of how to prepare and mix the medication) document to prepare the stock solution. RXM acknowledged the beyond used date printed on the bottle was more than 14 days and the white stains on the outer surfaces were due to multiple access and spills.

During an interview on 3/26/21, at 4:08 PM, with Assistant Director of Pharmacy (ADPS), ADPS stated the pharmacy would review the master formula for changes in the beyond use date of the folic acid liquid medication.

During a review of the 2014 version of United States Pharmacopeial (or USP, a drug compounding standards enforceable in the United States by the Food and Drug Administration which regulates safety of medication use) chapter 795 on non-sterile (clean) preparations guidance for dispensing medications, last accessed on

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| A 505 | Continued From page 269<br>4/5/21, the Guideline indicated, "The BUD (means Beyond Use Date) for water-containing oral (taken by mouth) formulations to be no later than 14 days when stored at controlled cold temperatures." | A 505 | | |
| A 507 | STOP-ORDERS FOR DRUGS<br>CFR(s): 482.25(b)(5)<br><br>§482.25(b)(5) - Drugs and biologicals not specifically prescribed as to<br>time or number of doses must automatically be stopped after a reasonable<br>time that is predetermined by the medical staff.<br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to implement a system, which required ordered medications to be reviewed, reordered, and stopped in accordance with the drug manufacturer's specifications and standards of practice for one of one sampled patient (Patient 68). This failure had the potential to result in a patient receiving less than optimal medical care and affect patient safety.<br><br>Findings:<br><br>During a review of Patient 68's Medication Administration Record (MAR), on 3/23/21, at 3:40 PM, the MAR indicated, "Patient 68 had 'stop orders' for most of his medications, which had not been reviewed or renewed by the physician for up to one year (365 days)."<br><br>During a concurrent interview and record review, with the Nurse Manager of the Surgical Unit (NMSU), and Registered Pharmacist Information Technology (RPHIT), Patient 68's MAR was reviewed. The MAR indicated all medications had | A 507 | | |

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a 365 day stop order. NMSU verified the findings and stated, "All home medications, (which could be any medications) had been given a 365 day stop order for all patients system wide."

During a concurrent interview and record review on 3/23/21, at 4 PM, with Assistant Director of Pharmacy Services (ADPS), of the hospital's most current "Drug Formulary List," undated, the Drug Formulary List, indicated, "There are several drugs with shorter stop dates per manufacturer's specifications:
1. Lovenox (Enoxaprin- an anticoagulant "blood thinner"), the manufacturer's package insert dated 3/2020 indicated, "the usual duration of administration is 7-10 days," yet the hospital had assigned a 365 stop order date for this drug.
2. Protonix (a medication for heartburn and helps prevent stomach and esophageal ulcers), the manufacturer's package insert dated 5/2012, indicated, "Protonix is indicated in adults and pediatric patients five years of age and older for the short-term treatment (up to eight weeks) in the healing and symptomatic relief of erosive esophagitis. For those adult patients who have not healed after eight weeks of treatment, an additional eight week course of Protonix may be considered. Safety of treatment beyond eight weeks in pediatric patients has not been established ....". The hospital assigned a stop order date of 365 days for this drug.
3. Imitrex (Sumatriptan- medication used to treat migraine headaches and/or cluster headaches), the manufacturer's package insert dated 12/2020, indicated, "The maximum daily dose is 40 mg (milligram, a unit of measurement) in a 24-hour period. The safety of treating an average of more than 4 headaches in a 30-day period has not been established."

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The ADPS acknowledged the findings and verified the hospital has not re-evaluated the dates on their drug stop orders for some of the medications in accordance with the drug manufacturer's recommendations for patient safety.

During an interview on 3/22/21, at 10:45 AM, with ADPS, ADPS stated, prior to 2019, the facility's policy and procedure for medication stop orders more accurately reflected the community standard, as the hospital had a 45 day medication stop order date renewal for all drugs. This allowed the prescribers in the hospital to review each patient's medication order, for the medications they are receiving and make a clinical decision about whether there was a medical need for each patient to continue on these medications. Other reasons for continually needing to re-evaluate each patient's medications, include: changes in patient conditions, renal impairment (when the kidneys fail to properly filter toxins and other waste products from the bloodstream) or hepatic impairment (the liver is unable to perform its normal metabolic functions), drug-to-drug interactions (combined effect of drugs taken concurrently), etc., all of which helps to optimize the highest level of patient care.

During a review of the facility's policy and procedure (P&P) titled, "Medication Administration," dated 6/19/19, the P&P indicated, "G. Automatic Medication Stop Orders: 1. All patient care orders will be reviewed and renewed every 365 days after the initial order in all patient care settings by the prescriber. Exception: Medications listed with shorter

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| A 507 | Continued From page 272<br>expiration dates, which will expire as listed below: a. Neuromuscular blocking agents-24 hours, b. Parental chemotherapy- 24 hours, c. Ketorolac- 5 days, d. Antibiotics- 7 days..." | A 507 | | |
| A 749 | INFECTION CONTROL PROGRAM<br>CFR(s): 482.42(a)(2)<br><br>The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;<br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to implement infection control practices as evidenced by:<br><br>1. Two Oscillator Ventilators (a breathing machine that delivers very small breaths very rapidly (180 to 900 breaths per minute to help with opening of collapsed lung tissue) had an outdated clean tags dated 6/13/18, and 8/27/19 and two Respironics V 60 Ventilators had no clean tags but were stored in the clean section of the respiratory equipment and storage room.<br><br>2. Several boxes of respiratory supplies were stored directly on the floor inside the respiratory equipment and storage room.<br><br>3. A bag of trash was left hanging in the corner of the three-tiered rack of clean respiratory supplies inside the respiratory equipment and storage room.<br><br>4. Several BIPAP (Bilevel positive airway pressure - a treatment that uses mild air pressure | A 749 | | |

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to keep airways open and helps one breathe) masks of different sizes containing specific manufacturer's storage specifications related to room temperature and humidity control were stored in the respiratory equipment and storage room that was not monitored for temperature and humidity control.

These failures had the potential to transmit infectious diseases.

Findings:

1. During a concurrent observation and interview on 3/30/21, at 7:12 PM, with Respiratory Therapist (RT) 2 and the Assistant Respiratory Therapy Manager (ARTM), two oscillator ventilators were found to have outdated clean tags. One oscillator ventilator had a tag dated 6/13/18, and the other oscillator ventilator had a tag dated 8/27/19. ARTM stated, "Those ventilators are no longer being used." RT 2 and ARTM verified the findings.

2. During a concurrent observation and interview on 3/30/21, at 7:25 PM, with RT 2 and ARTM, there were 11 boxes piled on top of each other stored directly on the floor. ARTM stated we will remove them.

During a concurrent observation and interview on 3/31/21 at 10 AM, with Registered Nurse (RN) 4, the 11 boxes found last night on the floor sill remained stored on the floor. RN 4 verified the findings.

3. During a concurrent observation and interview on 3/30/21, at 7:30 PM, with ARTM, a large clear trash bag filled with used gloves, used coffee

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| A 749 | Continued From page 274<br>cups, several papers, several used and contaminated oxygen tubings, ventilator tubings and connectors, were left hanging in the corner of the three-tiered rack with clean respiratory supplies. There was a large sign posted in the room, which read, "Please throw your trash outside." ARTM verified the findings and stated, "That should have been thrown outside."<br><br>4. During a concurrent observation and interview on 3/30/21, at 7:35 PM, with ARTM, there were several BIPAP masks of different sizes stored in the three-tiered rack of the respiratory equipment and storage room. ARTM verified the supplies had manufacturer's recommendations for storage related to temperature and humidity control requirement. ARTM was unable to provide documentation of a temperature and humidity control log for that room and he stated, "We have no thermostat in this room and we had not monitored this room for temperature and humidity control."<br><br>During an interview on 3/31/21, at 8:40 AM, with the Building Automation Technician (BAT), BAT stated the thermal-infrared thermometers that the facility used to check the ambient room temperatures were not accurate. The BAT stated they were off by 2-6 degrees. The BAT stated, "This room does not have a thermostat. The thermostat is located in the Environmental Service Office, which was adjacent to the respiratory equipment and storage room. We have no logs for the temperature and humidity control for this room." | A 749 | | |
| A1103 | INTEGRATION OF EMERGENCY SERVICES<br>CFR(s): 482.55(a)(2) | A1103 | | |

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| A1103 | Continued From page 275<br>[If emergency services are provided at the hospital --]<br><br>(2) The services must be integrated with other departments of the hospital.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and record review, the hospital failed to safely maintain two defibrillator units (devices that send electric shock to restart and makes the heart to go to a normal rhythm during an emergency situation) located on top of the emergency crash carts (drawers on wheels equipped with life-saving equipment and emergency medications) in the Emergency Department (or ED, a unit in hospital that provides urgent and quick care) Zone 1 and the 4th Tower Telemetry Unit (a hospital department where patients with medical conditions requiring constant monitoring of vital signs, heart rhythm, etc.) as evidenced by:<br><br>1. The weekly crash cart check for the ED Zone 1 and the 4th Tower Telemetry Unit were not completed.<br>2. The defibrillator on top of the ED crash cart in Zone 1 was not plugged into an electrical outlet to keep the device ready for emergency use.<br><br>These failures had the potential for this life saving equipment to not be ready and available in the event of an emergency.<br><br>Findings:<br><br>1. During a concurrent observation and interview, on 3/24/21, at 2:43 PM, in the 4th Tower Telemetry Unit, with Registered Nurse (RN) 9, the crash cart was observed to have a laminated | A1103 | | |

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instruction sheet for weekly manual check of the defibrillator. RN 9 stated, weekly manual defibrillator check and pacer testing required us to actually check the device but we were not required to document it.

During an interview on 3/24/21, at 2:45 PM, with Nurse Manager (NM) 2, NM 2 stated weekly defibrillator and pacer check was not documented on the crash cart log. NM 2 stated the procedure to perform weekly manual testing was posted on the defibrillator device, and she trusted her staff to make sure the device was in a good working condition.

2. During an observation on 3/25/21, at 11:31 AM, in the ED Zone 1, with the Director of Emergency Services (DES) and the ED Nurse Manager (EDNM), the defibrillator device on top of the crash cart number 26 was not plugged into an electrical outlet. The green check marks on the device that indicated readiness to be used was off or dark indicating it was not plugged in. DES and EDNM verified the findings.

During an interview on 3/25/21, at 11:42 AM, with EDNM, EDNM stated he was not sure how long and why the defibrillator was unplugged. He added that the device automatically performed daily self-check for proper functioning when plugged in an electrical outlet. EDNM stated the nursing staff documented the readiness and function of the defibrillator on the crash cart log. EDNM was not aware if a manual weekly defibrillator and pacer testing was done by the nursing staff.

During a review of the hospital's policy and procedure (P&P) titled, "Crash Carts", dated

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| A1103 | Continued From page 277<br>4/28/21, indicated, "Each unit will assign a staff member to check the crash cart integrity, defibrillator monitor functionality and sign the crash cart log. . . B. Manual Test Procedure: described the need for weekly defibrillator and Pacer testing. | A1103 | | |
| A1163 | ORDERS FOR RESPIRATORY SERVICES<br>CFR(s): 482.57(b)(3)<br><br>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the hospital failed to ensure Resident 1 (a first year physician-in-training in graduate medical education) was skilled, experienced, and knowledgeable in managing the respiratory care for one of one patient (Patient 1) in relation to the different oxygen modalities/therapies, intubation (a tube is inserted down the throat and into the windpipe to assist with breathing), mechanical ventilator (a machine that helps a patient breathe), ventilator settings (describe the pattern of breath delivery to a patient), and arterial blood gases (ABG -a blood test that measures its acidity, levels of oxygen and carbon dioxide) which were not ordered by a physician. This failure had the potential to place Patient 1 at risk for harm when there were no specific physician's orders for airway management and the safe initiation and management of mechanical | A1163 | | |

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| A1163 | Continued From page 278 | A1163 | | |

ventilation.

Findings:

During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure -a condition in which the heart's function as a pump is not enough to supply adequate amount of blood to the body) . . . brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60% (% of oxygen level in the blood, 60% or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95% on room air), and only improved to 70% with 15 L (liters, unit of measurement) NRB (non-rebreathing mask- a device used to assist in the delivery of higher concentration of oxygen). . . Vital signs were: HR (heart rate) 128 bpm (beats per minute, normal is about 60-100), RR (respiratory rate) 40 (normal is about 12-18), BP (blood pressure) 138/114 (normal is about 120/80). High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress. . . the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing), high flow nasal cannula, and eventually taking off the NRB mask. Patient was then later intubated (a tube is inserted down the throat and into the windpipe to assist with breathing) for respiratory

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failure and inability to tolerate BIPAP."

During an interview on 3/25/21, at 7 PM with Respiratory Therapist (RT) 1 and the Assistant Respiratory Therapist Manager (ARTM), RT 1 stated, "[Patient 1] came in severe respiratory distress, with very low oxygen saturation level. [Patient 1] was using his accessory muscles to breathe (an indicator of respiratory distress), and he stated, 'I could not breathe.' Initially, [Patient 1] was placed on BIPAP at 16 inspiratory pressure (makes breathing in easier) and 8 expiratory pressure (makes it easier to exhale), which I did not receive orders for. [Patient 1] was very restless and always takes his mask off, which caused his oxygen saturation level to drop more. [Patient 1] was placed on several oxygen therapies BIPAP, non-rebreather mask (a device that enables the delivery of high concentrations of oxygen), high-flow oxygen by nasal cannula, but the patient was not tolerating any of the oxygen therapies. The Patient was in distress. He was claustrophobic (abnormal dread of being in closed or narrow spaces). [Patient 1] needed to be intubated. I discussed this with the physician but I don't' remember documenting my conversation with the physician. I don't remember if I called them to the room. At 10 PM, Resident 1 intubated the patient with MD 5 in the room.

During a review of Patient 1's "Emergency Department Flowsheet," dated 12/21/20, with RT 1 and ARTM, the Emergency Department Flowsheet indicated, "At 7:08 PM, HR 130, RR 37, BIPAP, 94 % oxygen saturation. At 7:18 PM, HR 128, RR 40, non-rebreather mask, 97% oxygen saturation. At 7:21 PM labored, respiratory distress. At 8:16 PM, HR 115 RR 40, non-rebreather mask. At 8:23 PM, HR 113, RR

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46, High flow nasal cannula. At 8:25 PM, HR 122, RR 42 BP 70/48 (right leg). At 8:54 PM, HR 106, RR 44, BP 123/80 (right leg). At 9:15 PM, HR 107 RR 44, non-rebreather mask, O2 saturation 90% (percent). At 9:24 PM, nailbeds dusky (a sign of distress). At 9:44 PM, HR 116, RR 38, non-rebreather mask. At 10 PM, [Patient 1] was intubated by Resident 1.

During a concurrent interview and record review, Patient 1's "Respiratory Therapy Record" was reviewed. RT 1 and ARTM were unable to find a physician's order for the BIPAP, the NRB, the high flow oxygen by nasal cannula, the intubation, the mechanical ventilator and ventilator setting, and the arterial blood gases after NRB is placed. RT 1 stated, "There were also no orders given to draw arterial blood gases before and after intubation. Typically, the physician would enter the order." RT 1 and ARTM verified the findings.

During a review of the hospital's policy and procedure (P&P) titled, "Airway Management," dated 12/18/19, the P&P indicated, "A. Complete Physician Order: The physician shall specify the frequency, specific interventions and concomitant therapies necessary to provide comprehensive focused respiratory care. . ."

During a review of the hospital's policy and procedure (P&P) titled, "Non-Rebreather Mask," dated 12/18/19, the P&P indicated, "II. Stat (immediately, with no delay) ABG will be obtained after the NRB is placed. . ."

During a review of the hospital's policy and procedure (P&P) titled, "Oxygen Therapy," dated 12/18/19, the P&P indicated, "A. The physician shall specify the exact liter flow, oxygen

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| A1163 | Continued From page 281<br>percentage, or desired SpO2 to meet the physiologic needs of the patient. Monitoring arterial blood gases or pulse oximetry should be used as a guide for appropriate oxygen administration. . ." | A1163 | | |
| A1164 | RESPIRATORY SERVICES<br>CFR(s): 482.57(b)(4)<br><br>All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and record review, the facility failed to ensure all respiratory care services for one of one sampled patient (Patient 1) were documented in the patient's medical records. This failure had the potential for missed information necessary to provide appropriate patient care.<br><br>Findings:<br><br>During a review of Patient 1's "Emergency Documentation," dated 12/21/20, at 7:19 PM, the Emergency Documentation indicated, "A 58 year old male, with past medical history of COPD (chronic obstructive pulmonary disease - a progressive [gets worse over time] lung disease, which causes airflow blockage and shortness of breath), CHF (congestive heart failure -a condition in which the heart 's function as a pump is not enough to supply adequate amount of blood to the body), . . .brought in by ambulance for 10 hours of acutely worsening shortness of breath. Per the Emergency Medical Services (EMS), the patient had an oxygen saturation of 60 | A1164 | | |

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(Oxygen level in the blood. A reading of 60 mmHg or below indicates an extremely low oxygen level. Normal oxygen saturation is anything over 95% [percent]) on room air, and only improved to 70 with 15 L (liters, unit of measurement) NRB (non-rebreathing mask- a device used to assist in the delivery of higher concentration of oxygen). . .Vital signs were: HR (heart rate) 128 bpm (beats per minute), RR (respiratory rate) 40, BP (blood pressure) 138/114. High physical exam indicated the patient is working extremely hard to breathe, has coarse breath sounds bilaterally (both sides), and is in moderate distress. . .the patient was unable to tolerate BIPAP (BiLevel Positive Airway Pressure, a device that can push air into the lungs to improve one's breathing), high flow nasal cannula, and eventually taking off the NRB mask. Patient was then later intubated for respiratory failure and inability to tolerate BIPAP."

During a review of Patient 1's "Emergency Department Flowsheet," dated 12/21/20, with Respiratory Therapist (RT) 1 and Assistant Respiratory Manager (ARTM), the Emergency Department Flowsheet indicated, "At 7:08 PM, HR 130, RR 37, BIPAP, 94 % oxygen saturation. At 7:18 PM, HR 128, RR 40, non-rebreather mask, 97% oxygen saturation. At 7:21 PM labored, respiratory distress. At 8:16 PM, HR 115 RR 40, non-rebreather mask. At 8:23 PM, HR 113, RR 46, High flow nasal cannula. At 8:25 PM, HR 122, RR 42 BP 70/48 (right leg). At 8:54 PM, HR 106, RR 44, BP 123/80 (right leg). At 9:15 PM, HR 107 RR 44, non-rebreather mask, O2 saturation 90% (percent). At 9:24 PM, nailbeds dusky. At 9:44 PM, HR 116, RR 38, non-rebreather mask. At 10 PM, Resident 1 intubated [Patient 1]."

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| A1164 | Continued From page 283 | A1164 | | |

During an interview on 3/25/21, a 7 PM with Respiratory Therapist (RT) 1 and the Assistant Repiratory Therapist Manager (ARTM), RT 1 stated, "[Patient 1] came in severe respiratory distress, with very low oxygen saturation level. [Patient 1] was using his accessory muscles to breathe, and he stated, 'I could not breathe.' Initially, [Patient 1] was placed on BIPAP at 16 inspiratory pressure (makes breathing in easier) and 8 expiratory pressure (makes it easier to exhale), which I did not receive orders for. [Patient 1] was very restless and always takes his mask off, which caused his oxygen saturation level to drop. [Patient 1] was placed on several oxygen therapies BIPAP, non-rebreathing mask, high-flow oxygen by nasal cannula, but the patient was not tolerating any of the oxygen therapies. The Patient was in distress. He was claustrophobic (abnormal dread of being in closed or narrow spaces). [Patient 1] needed to be intubated. I discussed this with the physician but I don't' remember documenting my conversation with the physician. I don't remember if I called them to the room. At 10 PM, Resident 1 intubated the patient with MD 5 in the room. I remembered putting the patient on the ventilator but I don't remember documenting it. I also don't remember the ventilator setting because I did not chart them. I was called to see another patient and I failed to document. ARTM stated the staff are expected to document their observations, interventions, and complete the required documentation at the time of therapy initation.

During a concurrent interview and record review, on 3/25/21, at 7:20 PM, with RT 1 and ARTM, Patient 1's "Respiratory Therapy Record" was reviewed. RT 1 and ARTM were unable to find respiratory assessments, documentation of

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oxygen saturation after oxygen therapy was initiated, documentation of specific oxygen delivery for the device used, documentation of patient's condition during and after intubation, documentation of mechanical ventilator and its ventilator settings. RT 1 and ARTM verified the findings.

During a review of the hospital's policy and procedure (P&P) titled, "Documentation: Patient Care," dated 12/18/19, the P&P indicated, "All patients with prescribed respiratory care interventions will have their initial respiratory assessment completed at the time of therapy initiation by a Respiratory Care Practitioner. All patients will have ongoing assessments by a Respiratory Care Practitioner. . .Ongoing assessments will be completed once a shift, or frequently as dictated by patient's acuity. I. General Documentation A. Respiratory Therapy documentation will be performed in the online patient chart. . .III. Deviations from anticipated patient outcomes, adverse reactions, or decline in the patient's health status must be communicated to the RN and when appropriate the attending physician. This communication will be added to the documented assessment by the RCP."

During a review of the hospital's policy and procedure (P&P) titled, Airway Management," dated 12/18/19, the P&P indicated, "VIII. Record Keeping: A. Online documentation will be completed with each intervention in the respiratory Care section of the patient's electronic medical record. This will be utilized to complete focused notes for documenting breath sounds, sputum production, brief assessment of therapeutic efficacy and progress."