

February 6, 2023

Jie Wang, Health Facilities District Manager
Tatjana Eby-Siddiqui, District Administrator
CDPH Licensing and Certification Program
100 Paseo de San Antonio, Suite 235
San Jose, CA 95113

Re: Santa Clara Valley Medical Center (CMS Certification Number 050038)
Complaint No. CA00803062, CA00803450

Dear Mr. Wang and Ms. Eby-Siddiqui:

Enclosed please find Santa Clara Valley Medical Center's (SCVMC) responses to the Statement of Deficiencies (Form CMS-2567) that was received on January 26, 2023 and issued as a result of the CMS validation survey that ended on October 3, 2022. SCVMC has relevant supporting documentation, such as policies, forms, and monitoring instruments, available for review on-site.

SCVMC is the second largest public healthcare system in the State of California. It is the only safety net hospital system for the residents of Santa Clara County and surrounding communities, and it serves a large percentage of uninsured and underinsured patients, including the most vulnerable and complex patients in our community. SCVMC takes its responsibility to its patients very seriously. As you will see in our submission, SCVMC has undertaken extensive efforts to review and respond to every finding. The response constitutes SCVMC's credible allegation of compliance with the Medicare Conditions of Participation. However, this submission should not be viewed as an admission or agreement of the facts alleged or conclusions set forth in the Statement of Deficiencies, and SCVMC reserves its right to appeal.

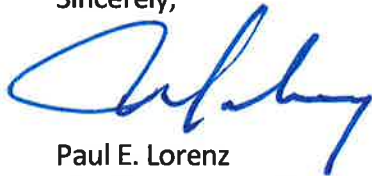
On behalf of the many dedicated staff members of SCVMC who have committed themselves to providing the highest quality of care to our patients and maintaining SCVMC's Medicare certification so that the hospital may continue to serve as a safety net provider in our community, we respectfully request that our submission be reviewed expeditiously and any necessary resurvey be conducted as soon as possible, so that we can demonstrate full compliance well in advance of April 25, 2023.

Please let us know immediately if you have any questions about our submission or need any additional documentation. You may direct any further communication to myself or:

Marites (Tess) Corpuz, MHA, BSN, RN, HACP, LSSGB
Interim Enterprise Quality Improvement Manager
Accreditation, Regulatory & Licensing
408-793-2118 | 408-375-6936
Marites.Corpuz@hhs.sccgov.org
2325 Enborg Lane, Suite 460
San Jose, CA 95128

Thank you very much.

Sincerely,



Paul E. Lorenz
Chief Executive Officer

Enclosures: Form CMS-2567 Response

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707



Refer to: WDSC-mc

Important Notice - Please Read Carefully

January 25, 2023

Administrator
Santa Clara Valley Medical Center
751 South Bascom Avenue
San Jose, CA 95128

Re: CMS Certification Number 050038
Complaint No. CA00803062, CA00803450
Conditions of Participation Not Met
Removal of Deemed Status and 90 Day Termination Track

Dear Administrator:

Section 1865 of the Social Security Act (the Act) and Centers for Medicare & Medicaid Services (CMS) regulations provide that a provider or supplier accredited by a CMS-approved Medicare accreditation program will be "deemed" to meet all of the Medicare Conditions of Participation (CoPs) for hospitals. In accordance with Section 1864 of the Act State Survey Agencies may conduct at CMS's direction surveys of deemed status providers/suppliers on a selective sampling basis, in response to a substantial allegation of noncompliance, or when CMS determines a full survey is required after a substantial allegation survey identifies substantial noncompliance. CMS uses such surveys as a means of validating the accrediting organization's survey and accreditation process.

A survey conducted by the California Department of Public Health at Santa Clara Valley Medical Center on October 3, 2022 found that the facility was not in substantial compliance with the following CoPs for hospitals.

482.12 Governing Body
482.13 Patient Rights
482.21 Quality Assessment and Performance Improvement
482.23 Nursing Services
482.41 Physical Environment

As a result, effective the date of this letter, your deemed status has been removed and survey jurisdiction has been transferred to the California Department of Public Health. A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction.).

A Life Safety Code survey completed on 09/21/2022 also found Santa Clara Valley Medical Center to be out of compliance with the provisions of the National Fire Protection Association's Life Safety Code (2012 edition), which are included in the Medicare health and safety regulatory requirements for hospitals. See 42 C.F.R. § 482.41(b). The findings of the Health and Life Safety Code survey are also enclosed, Statements of Deficiencies, Form CMS-2567.

When a hospital, regardless of whether it has deemed status, is found to be out of compliance with the CoPs, a determination must be made that the facility no longer meets the requirements for participation as a provider or supplier of services in the Medicare program. Such a determination has been made in the case of Santa Clara Valley Medical Center and accordingly, the Medicare agreement between Santa Clara Valley Medical Center and CMS is being terminated.

The date on which the Medicare agreement terminates is April 25, 2023.

The Medicare program will not make payment for services furnished to patients who are admitted on or after April 25, 2023. For inpatients admitted prior to April 25, 2023, payment may continue to be made for a maximum of 30 days of inpatient services furnished on or after April 25, 2023.

Termination can only be averted by correction of the deficiencies, through submission of an acceptable plan of correction (PoC) and subsequent verification of compliance by the California Department of Public Health. The Form CMS 2567 with your POC, dated and signed by your facility's authorized representative must be submitted to CDPH, San Jose district office, no later than 10 days from the date you receive this letter. Please indicate your corrective actions on the right side of the Form CMS-2567 in the column labeled "Provider Plan of Correction", and list the corresponding deficiency number in the column to its left, labeled "ID Prefix Tag". Additionally, indicate your anticipated completion dates in the column labeled "Completion Date".

An acceptable PoC must contain the following elements:

1. The plan for correcting each specific deficiency cited;
2. The plan for improving the processes that led to the deficiency cited, including how the hospital is addressing improvements in its systems in order to prevent the likelihood of recurrence of the deficient practice;
3. The procedure for implementing the PoC, if found acceptable, for each deficiency cited;
4. A completion date for correction of each deficiency cited;
5. The monitoring and tracking procedures that will be implemented to ensure that the PoC is effective and that the specific deficiency(ies) cited remain corrected and in compliance with the regulatory requirements; and
6. The title of the person(s) responsible for implementing the acceptable PoC.

Copies of the Form CMS-2567, including copies containing the facility's PoC, are releasable to the public in accordance with the provisions of Section 1864(a) of the Act and 42 CFR 401.133(a). As such, the PoC should not contain personal identifiers, such as patient names, and you may wish to avoid the use of staff names. It must, however, be specific as to what corrective action the hospital will take to achieve compliance, as indicated above.

Your facility will be revisited to verify necessary corrections. If CMS determines that the reasons for termination remain, you will be so informed in writing, including the effective date of termination. If corrections have been made and your facility is in substantial compliance, the termination procedures will be halted, and you will be notified in writing.

If your Medicare agreement is terminated and you wish to be readmitted to the program, you must demonstrate to the CDPH and CMS that you are able to maintain compliance. Readmission to the program will not be approved until CMS is reasonably assured that you are able to sustain compliance.

If you have any questions regarding this matter, please contact the CMS, San Francisco location by phone at 415-744-3727 or by e-mail at Maureen.Calacal@cms.hhs.gov.

Sincerely,

Renae Hill

Renae Hill
Manager
Acute & Continuing Care Branch
San Francisco & Seattle

Enclosures: CMS Form-2567 Statement of Deficiencies

cc: State Survey Agency
Accrediting Organization

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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|--|--|
| NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128 |
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| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE |
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| A 000 | <p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during a complaint validation survey conducted from 9/20/22 to 10/3/22.</p> <p>The hospital was licensed for beds 665 and the census at the time of the survey was 382. The sample size was 51.</p> <p>For Complaint CA00803062 regarding Quality of Care/Treatment and Entity Reported Incident (ERI) CA00804102 regarding Quality of Care/Treatment, four Conditions of Participation were not met (42 CFR §482.12 Governing Body, §482.13 Patient's Rights, §482.21 Quality Assessment and Performance Improvement Program [QAPI], and §482.23 Nursing Services) and federal deficiencies were identified.</p> <p>For Complaint CA00801857 regarding Physical Environment, ERI CA00801861 regarding Physical Environment, and Complaint CA00803450 regarding Physical Environment, federal deficiencies were identified.</p> <p>Inspection was limited to the specific Conditions of Participation authorized by CMS (Governing Body, Patient's Rights, Quality Assessment and Performance Improvement Program (QAPI), Nursing Services, Medical Records Services, and Physical Environment).</p> <p>Representing the California Department of Public Health: 25438, Health Facilities Evaluator Nurse; 38174, Health Facilities Evaluator Nurse; 38573, Health Facilities Evaluator Nurse; 32398, Health Facilities Evaluator Nurse; 44577, Health</p> | A 000 | <p>Preparation and execution of this Plan of Correction does not constitute an admission or agreement of the facts alleged or conclusions set forth in the Statement of Deficiencies. This Plan of Correction is prepared and executed solely because it is required by federal or state law. The following constitutes Santa Clara Valley Medical Center's credible allegation of compliance.</p> | |

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|--|---|--------------------------------|
| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Paul E. Lorenz  | TITLE Chief Executive Officer | (X6) DATE 02/06/2023 |
|--|---|--------------------------------|

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

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| A 000 | Continued From page 1 Facilities Evaluator Nurse; 45971, Medical Consultant; 41149, Medical Consultant; 43380, Life Safety; and 37295, Medical Records Consultant. | A 000 | | | |
| A 043 | GOVERNING BODY CFR(s): 482.12 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 ... This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to ensure compliance with all Conditions of Participation. This resulted in three condition-level deficiencies (Patient Rights, Nursing Services, and Quality Assessment and Performance Improvement Program). The governing body failed to fully address serious, systemic, and recurring issues, placing nineteen of 51 sampled patients at risk for adverse events. Findings: 1. Failure to protect and promote each patient's rights (refer to A-0115). 2. Failure to ensure that nursing services were provided to meet the needs of patients (refer to A-0385). 3. Failure to carry out an effective, system-wide quality assessment and performance | A 043 | (Please see Attachment A, pg. 1-2) | | |

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| A 043 | Continued From page 2 improvement program (refer to A-0263). The governing body failed to implement an effective system that provided for oversight of staffing and maintenance of a safe environment for all patients. These cumulative failures resulted in the hospital's inability to ensure patient safety and quality of care. | A 043 | (Please see Attachment A, pg. 1-2) | |
| A 084 | CONTRACTED SERVICES CFR(s): 482.12(e)(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to evaluate two contracted services annually. This deficient practice had the potential for the governing body to be unaware of whether contracted services were provided in a safe and effective manner to patients. Findings: During an interview on 9/26/22 at 10:31 a.m. with the Chief Operating Officer (COO), the COO stated every contract is supposed to undergo a performance review annually at minimum. During a review of the hospital's policy and procedure titled Policies on Soliciting and Contracting, revised 5-24-22, indicated, "... Monitoring, administration and evaluation of County contracts are essential ... to ensuring that the County receives the goods and/or services | A 084 | (Please see Attachment A, pg. 2-4) | |

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| A 084 | <p>Continued From page 3</p> <p>for which it contracts ... Agencies/Departments are required to develop performance standards and implement a process that incorporates monitoring, administration and evaluation of contracts ... Agencies/Departments must also document their performance evaluations of contractors ... These performance evaluations may be used by Agencies/Departments to evaluate the propriety of entering into contract extensions or future agreements with the same contractor. The Board or Board Committees may also request copies of evaluations from time to time ...".</p> <p>During a review of the hospital's governing body bylaws, dated December 15, 2020, indicated the Chief Executive Officer was responsible for maintaining a list of all contracted services and providing the Governing Body with "... information that the services performed under contracts are provided in a safe and effective manner ...".</p> <p>During an interview on 9/27/22 at 9:45 a.m. with the COO and the Director of Contracts (DCTS), the COO stated the hospital's Chief Executive Officer (CEO) has the authority to review the performance of all contracts to see if the contracted services are performed in a safe and effective manner.</p> <p>During a review of the hospital's medical gas contract indicated it is effective from December 1, 2020 to November 30, 2025. During a review of the hospital's contract to purchase C-arm [a mobile device used to take images during procedures] diagnostic imaging equipment, service, and maintenance indicated it is effective from July 1, 2020 to June 30, 2025.</p> | A 084 | (Please see Attachment A, pg. 2-4) | | |

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| A 084 | <p>Continued From page 4</p> <p>During an interview on 9/27/22 at 4:20 p.m. with the COO, the COO confirmed there was no medical gas contract evaluation and no C-arm contract evaluation for 2021 to 2022.</p> <p>During an interview on 9/27/22 at 4:59 p.m. with the COO, the COO confirmed there was no medical gas contract evaluation and no C-arm contract evaluation for 2020 to 2021. When asked if the hospital was supposed to have completed contract evaluations for the medical gas contract and the C-ARM contract, the COO stated yes because the evaluations were supposed to be filled out annually.</p> <p>During a concurrent interview and record review on 9/30/22 at 11:09 a.m. with the COO, Chief Procurement Officer for the county, Supervisor of Respiratory Care Services (SRC OO), and the Operating Room Director (MD PP), the hospital's policy and procedure titled Policies on Soliciting and Contracting, revised 5-24-22, was reviewed. The COO confirmed that the policy's statement " ...Agencies/Departments must also document their performance evaluations of contractors ..." meant the hospital is expected to fill out the Contract Monitoring Tool for all contracts annually. The COO stated the hospital does not have completed Contract Monitoring Tool forms for the medical gas contract and the C-arm contract. The SRC OO stated he does not fill out any evaluation forms on how well the medical gas contractor is doing. The SRC OO stated there was no formal evaluation process for the medical gas contract. The SRC OO stated the Enterprise Director of Ancillary Services would be the staff member communicating with the CEO</p> | A 084 | (Please see Attachment A, pg. 2-4) | |
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| A 084 | Continued From page 5 about the hospital's satisfaction with the medical gas contract. When asked how often the Enterprise Director of Ancillary Services reports to the CEO about the medical gas contract, the SRC OO stated he did not know. The SRC OO stated he would think there were no reports to the CEO because he has never had to escalate any issues. MD PP stated there was no formal process for evaluating the C-arm contract. MD PP stated she has regular meetings with the CEO about contracts, but stated she does not have a formal tracking system showing she has discussed all of her contracts with the CEO. During a review of the hospital's Contract Monitoring Tool, undated, indicated the tool asked "... Did the Contractor meet the objectives/scope of services in a satisfactory manner? Timeliness? Quality of Care? Availability? ... Did you or anyone else encounter any issues/problems with the quality of services provided? ... Were county required compliance and performance standards met? ... Are there any other concerns with this Contractor? ...". | A 084 | (Please see Attachment A, pg. 2-4) | | |
| A 115 | PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to comply with the Condition of Participation for Patient Rights as evidenced by: 1. Failure to inform of Patient Rights (refer to A-0117) | A 115 | Please see Attachment A, pg. 4 and please refer to tags: A117 pg. 4-7 A144 pg. 8-14 A172 pg. 14-15 A174 pg. 15-16 | | |

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| A 115 | Continued From page 6 2. Failure to provide care in a safe environment (refer to A-0144) 3. Failure to assess and evaluate use of restraint (refer to A-0172) 4. Failure to provide criteria in discontinuing restraint (refer to A-0174). The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe environment. | A 115 | Please see Attachment A, pg. 4 and please refer to tags: A117 pg. 4-7 A144 pg. 8-14 A172 pg. 14-15 A174 pg. 15-16 | | |
| A 117 | PATIENT RIGHTS: NOTICE OF RIGHTS CFR(s): 482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure two sampled patients (Patient 15 and 35) were informed of their rights in furnishing care according to the hospital's policy and procedure when: 1. For Patient 15, the Condition of Admissions provided and signed by Patient 15 was not in the patient's language 2. For Patient 35 patient did not receive information for Patient Rights. These failures resulted in not protecting the | A 117 | (Please see Attachment A, pg. 4-7) | | |

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| A 117 | <p>Continued From page 7</p> <p>patients' rights to be informed in a language of their preference and potentially deny patients the opportunity to make informed choices regarding their care.</p> <p>Findings:</p> <p>1. Review of Patient 15's demographic record indicated a need for Vietnamese interpreter.</p> <p>Review of Patient 15's Condition of Admission dated 9/1/22 indicated Patient 15 signed the form in a different language version (Spanish).</p> <p>During a concurrent interview and record review with the Director of Admitting J (DA J) on 9/23/22 at 10:55 a.m., she confirmed the Condition of Admission form provided to Patient 15 was not in the patient's language and it was a mistake by the admitting hospital person. DA J stated the Condition of Admission form is available in Patient 15's language.</p> <p>Review of the hospital's policy, "Rights and Responsibilities of Patients", dated 8/19/17, indicated copy of patient rights and responsibilities are available in English, Spanish, and Vietnamese.</p> <p>2. Patient 35 was admitted to the hospital on 11/17/2021.</p> <p>During a review of Patient 35's electronic record on 9/27/22 with Sepsis QI coordinator Y (QC Y), the electronic record did not indicate that Patient 35 received a copy of the facility's Patient Rights.</p> <p>During an interview on 9/27/22 at 2:46 p.m., with QC Y, she stated, Patient 35 did not have a copy</p> | A 117 | (Please see Attachment A, pg. 4-7) | |

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| A 117 | Continued From page 8 of Patient Rights signed, it was in a que for admitting department. During an interview on 9/29/22 at 10:02 a.m., with the manager of admitting & ED registration DD (MA DD), MA DD stated she does not believe there is a copy of Patient Rights. During an interview on 9/29/22 at 1002, with the computer operator EE (CO EE), CO EE stated, she did not see the Patient Rights document for Patient 35 in the computer. During a review of the hospital's policy and procedure (P&P) titled, Rights and Responsibilities of Patients revised 8/9/2017, the P&P indicated at the time of admission, or as soon as reasonably possible after admission, (sic) provides the patient/legal representative or significant other with a copy of the "Patient Rights and Responsibilities" included in patient rights section of Patient Information Booklet ... | A 117 | (Please see Attachment A, pg. 4-7) | | |
| A 144 | PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2) The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on observation, interview and record review, the hospital failed to ensure eight patients (1, 16, 39, 40, 41, 42, 43, and 44) were cared for in a safe environment: 1. For Patient 1, environmental safety concerns were not identified and corrected. This failure resulted in Patient 1, a suicidal patient having the means and opportunity to throw a hospital room chair through the window and jump out leading to | A 144 | (Please see Attachment A, pg. 8-14) | | |

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

PRINTED: 10/26/2022
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| A 144 | Continued From page 9 Patient 1's death; 2. Patient 16, who was placed on a 5150 hold (when a designated professional evaluates a person to be a danger to self or to others due to a mental health disorder, the person can be detained for a 72-hour psychiatric hospitalization), was not constantly observed. This failure resulted in Patient 16 eloping from the emergency department (ED) and jumping from a parking structure, which caused injuries including multiple facial fractures (broken bone), pelvis fracture, wrist fracture, foot fracture, pulmonary contusions (bruises), pneumothorax (collapsed lung), retroperitoneal hematoma (bleeding in part of the abdominal cavity). During Patient 16's three-month hospitalization, he was admitted to the Intensive Care Unit (ICU), was placed on a ventilator (machine that helps a person breathe), and required a feeding tube for nutrition. Patient 16 was also diagnosed with closed head injury (injury to the brain with no break in the skull), severe traumatic brain injury (damage to the brain caused by an external force), hypoxic-ischemic infarcts (death of tissue due to inadequate oxygen in the blood and inadequate blood supply), altered mental state (symptoms that can range from confusion to loss of consciousness), lactic acidosis (buildup of lactic acid in the bloodstream), oropharyngeal dysphagia (swallowing problems in the mouth and/or throat), voice and resonance disorder (disorder that affects the quality of the voice during speech), cognitive communication deficit (difficulty communicating), and difficulty walking. Patient 16 required multiple surgeries and extensive rehabilitation treatments over several months. | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 10</p> <p>3. For Patients 1, 16, 39, 40, 41, 42, 43, and 44, staff did not intervene when eight patients eloped while on an involuntary hold. This failure had the potential to result injury or death to other patients.</p> <p>Findings:</p> <p>1. Record review on 9/20/22 at 11:00 a.m. indicated Patient 1 was admitted to the hospital on 8/12/22 for self-inflicted stab wounds to the abdomen and wrist from a suicide attempt. Patient 1 had been placed on a 5150 hold by law enforcement. A 5150 is a 72 hour hold when a patient is considered a danger to self or others.</p> <p>Patient 1 was brought to the operating room for repair of the lacerations to his abdomen and wrist. Patient 1 was then brought to the forth floor medical surgical unit for his recovery.</p> <p>Record review on 9/20/22 at 11:30 a.m. of a Patient Care Overview, dated 8/12/22 at 10:25 p.m. indicated Patient 1 was on 5150 hold and had a 1:1 sitter at the bedside. "Patient denied suicidal ideation, stated the voices come and go, but no current thought or plan of harming himself."</p> <p>Record review of a nurses note dated 8/13/22 at 5:11 am indicated, "Patient denies SI/HI [suicidal/homicidal ideations] but states he is still hearing voices that are telling him he should have gone to the hotel. 1:1 sitter at bedside for 5150 DTS [danger to self]."</p> <p>Record review at 11:45 a.m. of the Initial Psych</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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

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| A 144 | <p>Continued From page 11</p> <p>Consult Note dated 8/13/22 at 2:13 p.m. indicated Patient 1 "presenting with self-inflicted slab wounds in response to incessant command auditory hallucinations telling him to kill himself."</p> <p>Patient 1's stated chief complaint was "The voices were telling me you have only 8 more days to kill yourself. The next day they would say that I have only 7 more days."</p> <p>Further record review of the Course, Assessment and Plan indicated, "Patient has a history of treatment resistant Schizoaffective Disorder. We will extend his 5150 hold onto 5250 [5250 extends the hold to 14 days]."</p> <p>Further record review indicated Patient 1 continued to have a 1:1 sitter at all times and record review on 9/20/22 at 12:00 p.m of the Death Summary indicated, "On the evening of 8/17/22 at approximately 20:56 (8:56 p.m.) Code Gray was called as the patient was found to be agitated and physically assaulting the sitter in his room."</p> <p>"The RN had to physically pull the sitter from the room for her safety as she was actively being hit by the patient. The patient tried to lunge at staff and the door was closed for the staff safety. The door remained closed for approximately 5 seconds and when it was reopened, the patient was seen back near his bed and appeared to be searching for something while continuing to yell. He then grabbed a chair, lifted it, and broke the window open with the chair. He then proceeded to jump out the window of his room on the 4th story of building E. MD was notified the patient had been pronounced dead on the scene at</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | <p>Continued From page 12 21:12 (9:12 p.m.) by EMS [emergency medical services]."</p> <p>Record review the same day at 12:30 p.m. of the Inpatient Psychiatry Consult Note dated 8/17/22 at 9:12 p.m. indicated, "Patient 1 was seen between 2 - 3 p.m. Patient 1 was seated in his chair. Patient complained about his abdomen being distended. He appeared calm but anxious. He acknowledges auditory hallucinations."</p> <p>"I reassured him that we were working on getting him admitted to a psychiatric facility so that he can receive appropriate help."</p> <p>During an interview on 9/21/22 at 10:45 a.m., Sitter C stated she was the sitter for Patient 1 on the evening of 8/17/22. Sitter C stated Patient 1 had gone into the bathroom and when he came out, he stated he was bleeding. Sitter C stated she asked to see and Patient 1 attacked her. Sitter C stated staff rushed to pull her out of the room as Patient 1 took the chair and hit the window and jumped.</p> <p>During an observation and interview on 9/23/22 at 2:30 p.m., assistant nurse manager (ANM) on the 4th floor medical-surgical unit stated she had been the charge nurse on the evening of 8/17/22. She stated she had been at the nurses station and heard yelling and realized it was Patient 1. Staff responded and had trouble opening the door of Patient 1's room. She stated she could see Patient 1 blocking the door and hitting Sitter C.</p> <p>ANM stated she yelled for help and called Code Grey for security. She stated staff assisted Sitter</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 | <p>Continued From page 13</p> <p>C to exit the room and she could see Patient 1 pacing in the room. ANM stated Patient 1 picked up the hospital chair, broke the window, and jumped to his death.</p> <p>ANM stated in less than a minute EMS responded to the construction area where Patient 1 had fallen and Patient 1 was unable to be revived.</p> <p>ANM stated the hospital room was presently set up the same way as it had been when Patient 1 was present. The room contained a bed, a computer on wheels, IV pump, cords for the nurses call light and computer, and a padded chair.</p> <p>ANM stated the rooms were furnished the same way for all patients and the chair was a typical hospital room chair and could be moved around the room.</p> <p>During an observation at the same time, the chair could be lifted and was not anchored to the floor.</p> <p>Record review on 9/23/22 at 3:00 p.m. of the At-Risk Safety checklist (every shift) indicated from 8/12/22 until 8/17/22 the points for assessment of the room safety were determined as 'met'.</p> <p>During an interview on 9/26/22 at 9:45 a.m., MD F indicated Patient 1 was very ill, but calm, more so depressed. MD F stated Patient 1 wouldn't have hurt himself except he could not resist the voices telling him to do so.</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 14</p> <p>Record review on 9/26/22 at 11:00 a.m. of the Hospital Policy "Suicide/Safety Precautions and Care of Patient in Non- Behavioral Health Areas dated 6/24/2020 indicated: " A. Suicidal, potentially suicidal, and patients with self-harming behaviors will be treated in a safe environment to protect the patient from self harm. B. Special safeguards will be provided to protect the patient from self harm when the patient is assessed to be suicidal, potentially suicidal, and/or endanger of self harm."</p> <p>Further record review of the policy contained the "Environment of Care Checklist for Safety of Suicidal Patients and Patients with Self-Harming behavior. This checklist is a tool and should be used to identify and correct any environmental safety concerns to prevent inpatient suicide attempts. Documentation of the points below will be performed in the electronic medical record."</p> <p>The points indicated in the policy included: "4. Is the area free of lamps, any any items that could be used as a weapon? ... 6. Is furniture secured or heavy enough to prevent it from being picked up and thrown or moved to block door?"</p> <p>2. Review of Patient 16's ED Provider Notes from a previous hospital, dated 5/12/21 at 9:56 p.m., indicated the following: Patient 16 was a 19-year-old male with diagnoses including Coronavirus 2019 (COVID-19, a new strain of virus that can cause mild to severe illness) and adjustment disorder (emotional or behavioral symptoms in response to being unable to cope with a source of stress). Patient 16 was brought to a previous hospital's ED "by ambulance after he was found running</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 15 around the street naked. Per EMS [Emergency Medical Services] PD [police department] apprehended him, remove handcuffs, patient took off running, and thus was taken down." Patient 16 was placed on a 5150 hold for gravely disabled and danger to self. On 5/13/21 at 11:28 a.m., prior to being transferred from a previous hospital to this hospital, "Patient 16 ran out of [a previous hospital's] emergency department, security guard cannot catch up and he got away. Police and EMS found him down the street ... he is otherwise going to be going to EPS [Emergency Psychiatric Services] at this time."</p> <p>Review of Patient 16's Application for Assessment, Evaluation, and Crisis Intervention or Placement for Evaluation and Treatment (also known as 5150 or psychiatric hold), dated 5/12/21 at 11 p.m., indicated Patient 16 was a danger to himself and was a gravely disabled adult because Patient 16's "father and mother concerned as he asked his father to choke and kill him, wanted to take the Samurai sword to stab himself, and said he wished they had a gun so he could blow his head off."</p> <p>Review of the previous hospital's Patient Care Timeline, dated 5/12/21 to 5/13/21 indicated Patient 16 was discharged from the previous hospital on 5/13/21 at 12:03 p.m.</p> <p>Review of Patient 16's EPS Notes, dated 5/13/21 at 1:30 p.m., indicated Patient 16 was seen for an initial RN assessment.</p> <p>Review of Patient 16's EPS Provider Notes, dated 5/13/21 at 3:38 p.m. indicated Patient 16</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 | <p>Continued From page 16</p> <p>had a temperature of 101.5, was coughing, and complaint of malaise. The notes indicated the plan was to send Patient 16 to the ED for medical clearance, continue with 5150, and the Patient 16 can be sent back to EPS after medical clearance.</p> <p>Review of Patient 16's EPS Notes, dated 5/13/21 at 5:25 p.m. indicated EPS Registered Nurse (EPS RN) escorted Patient 16 to the ED with one EPS mental health worker, a protective services officer, and ED tech due to AWOL (absent without official leave) risk. The notes indicated EPS RN, "Gave SBAR [Situation, Background, Assessment, Recommendation, a communication tool] report to Assigned male nurse [Registered Nurse T (RN T)] and notified him of [Patient 16's] high potential AWOL risk due to him awoling from prior ED prior to EPS."</p> <p>Review of the County Protective Services Incident Report, dated 5/13/21 indicated Protective Services Officer (PSO) documented, "On Thursday 5/13/21 at approximately 1720 [5:20 p.m.] Hours ... I was dispatched to take [Patient 16] from Emergency Psychiatric services (EPS) overflow unit to the Emergency room (ER) Due to COVID like symptoms. Upon arrival staff informed me that the patient was a flight risk, he was then secured to the chair for transport to the Emergency room. Patient [16] went to Emergency Room 19, upon arrival I informed the ER staff [RN T] that [Patient 16] was a flight risk and could possibly try to elope. Staff put the patient in the room and then assigned a sitter for the patient no restraints or medication was given at the time.</p> <p>Review of Patient 16's Patient Care Timeline</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 | <p>Continued From page 17 from Patient 16's first visit to this hospital's ED, dated 5/13/21, indicated the following: On 5/13/21 at 5:43 p.m., Patient 16 arrived in this hospital's ED. On 5/13/21 at 5:59 p.m., Patient 16's EPS Legal Status was "5150" and the reason for 5150 was "Danger to Self; Gravely Disabled." On 5/13/21 at 6 p.m., RN T documented, "[Patient 16] remains 5150, sitter present at bedside." On 5/13/21 at 6:10 p.m. RN T documented, "[Medical Doctor VV (MD VV) reports contacted EPS MD and reports ok to transfer pt [Patient 16] back to EPS." On 5/13/21 at 6:30 p.m., RN T documented, "Sitter present; awaiting transfer to EPS." On 5/13/21 at 6:33 p.m., RN T documented, "[EPS] RN reports bed not available until 1900 [7 p.m.]." On 5/13/21 at 6:55 p.m., RN T documented, "[At] approximately 1847 [6:47 p.m.] Pt [Patient 16] removed IV [intravenous catheter placed in the vein to administer fluids or medication] and exited assigned room and exited ER [emergency room]. Pt not receptive to verbal redirection to return to assigned room. Pt continues to refuse verbal redirection and ran out of ER. 3 ER Staff followed pt past ED CT [computed tomography]. Continued to provide verbal redirection and encouragement to return to ER, pt continues to run and observed pt running toward M building where pt [patient] is longer visible." During observation of 5/13/21 ED video surveillance on 9/26/22 at 11:58 a.m. and concurrent interview with the Emergency Department Nurse Manager S (NM S), the Director of Nursing Critical Care (DNCC), RN T,</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | Continued From page 18 and Registered Nurse U (RN U), the following was observed: On 5/13/21 at 6:39:59 p.m., Patient 16 walked out of his room wearing light blue-green scrubs, while Sitter X sat at a workstation on wheels (WOW) with his back toward the door of Patient 16's room. On 5/13/21 at 6:40:04 p.m., Patient 16 walked past Sitter X. On 5/13/21 at 6:40:07 p.m., Patient 16 walked past RN U, who was talking to a staff member by the nurse's station, and Patient 16 continued walking down the hallway. On 5/13/21 at 6:40:09 p.m., Patient 16 walked out of video view. Sitter X remained seated at the WOW and RN U continued speaking to another staff member. On 5/13/21 at 6:40:22 p.m., RN U grabbed supplies and walked down the hallway towards Patient 16's room. On 5/13/21 at 6:40:45 p.m., a janitorial staff member and RN U looked towards Patient 16's room. RN U pointed in the direction of Patient 16's room. On 5/13/21 at 6:40:53 p.m., Sitter X looked inside Patient 16's room. On 5/13/21 at 6:41:03 p.m., Sitter X got up from the chair and walked down the hallway. On 5/13/21 at 6:41:17 p.m., RN U looked inside patient room. RN T came into video view. On 5/13/21 at 6:41:24 p.m., RN T came out of video view. On 5/13/21 at 6:42:15 p.m., after leaving another ED room, RN U stood by the nurse's station. On 5/13/21 at 6:42:55 p.m. Patient 16 walked down the hallway toward his room with Sitter X behind him. On 5/13/21 at 6:43:06 p.m., Sitter X brought | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 19</p> <p>Patient 16 back to his room.</p> <p>On 5/13/21 at 6:43:18 p.m., Sitter X closed the door to Patient 16's room.</p> <p>On 5/13/21 at 6:43:40 p.m., Sitter X walked away from Patient 16's room.</p> <p>On 5/13/21 at 6:43:43 p.m., Sitter X walked past RN U, who remained at the nurse's station.</p> <p>On 5/13/21 at 6:43:45 p.m., Sitter X walked out of video view.</p> <p>On 5/13/21 at 6:44:18 p.m., Sitter X walked back toward Patient 16's room.</p> <p>On 5/13/21 at 6:44:25 p.m., Sitter X placed an item on the WOW in front of Patient 16's room and walked away from Patient 16's room. Sitter X walked past RN U.</p> <p>On 5/13/21 at 6:44:29 p.m., Sitter X walked out of video view.</p> <p>On 5/13/21 at 6:44:44 p.m., RN U walked out of another ED room.</p> <p>On 5/13/21 at 6:44:48 p.m., Patient 16 opened the door to his room.</p> <p>On 5/13/21 at 6:44:52 p.m. Patient 16 stepped out of the room and turned toward RN U.</p> <p>On 5/13/21 at 6:44:57 p.m., RN U pointed toward Patient 16's room and Patient 16 turned his back to RN U.</p> <p>On 5/13/21 at 6:45:02 p.m., Patient 16 walked through exit doors. RN U followed behind Patient 16.</p> <p>On 5/13/21 at 6:45:05 p.m., RN T and another staff member followed Patient 16 through the exit doors.</p> <p>From 5/13/21 at 6:44:29 p.m. to 5/13/21 at 6:45:17 p.m., Sitter X was not in video view.</p> <p>RN T stated he was Patient 16's assigned nurse. RN T stated he was not aware Patient 16 eloped at a prior hospital prior to coming to this hospital's</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 | <p>Continued From page 20</p> <p>ED. He stated when patients are on 5150 or come from EPS, patients are given scrubs to wear in a specific "teal" color, so staff can identify them. RN U stated Patient 16 was already wearing the distinct color scrubs when he came from EPS. RN U stated it was noticeable to see a patient in those colored scrubs, but he did not notice Patient 16 walk to the bathroom. RN T stated he did not notice Patient 16 walk to the bathroom. RN T stated he was at the nurse's station and did not see Patient 16 nor Sitter X walk by. RN U stated when he noticed Patient 16 was gone, he told Sitter X to locate the patient. RN U stated he remembered having a conversation with Sitter X saying he should be with the patient all the time. RN U stated he kept that information between him and Sitter X. RN T stated he was not informed Patient 16 left his room and went to the bathroom unsupervised. RN U stated if he felt the sitter could do his job, he would not escalate the sitter's lapse to the charge nurse. RN U stated after Patient 16 was returned to his room, he did not see Sitter X walk away from the Patient 16's room. RN U stated when caring for 5150 patients, he relies on the sitter and stated Sitter X did not say anything to him. NM S stated she did not expect the sitter's lapse to be escalated to the charge nurse because Patient 16 was found.</p> <p>During an interview on 9/22/22 at 3:36 p.m., with NM S and the DNCC, NM S stated they do their best to find a room close to the nurse's station for 5150 patients. NM S stated the ED has a high volume of patients, so they put 5150 patients in any room available. The DNCC stated they assign a sitter for 5150 patients and the 5150 patients are given scrubs to identify that identify</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 21 that they are 5150 patients. The DNCC stated a safety sweep of the room should be done to remove anything unnecessary. She stated the sitter providing constant observation should be within arms reach of the patient. The DNCC stated in this case, Patient 16 had COVID-19, so the sitter's expectation was to be outside the door with the door closed and to visualize the patient through the window on the door. She stated Sitter X should have had the appropriate PPE, an N95. The DNCC stated Sitter X had his back towards the door and was not paying attention to Patient 16. She stated Sitter X returned Patient 16 to the room. NM S stated Sitter X left the patient to look for an N95.</p> <p>During an interview on 9/22/22 at 11 a.m., RN T stated he did not remember how he was assigned or informed about Patient 16. RN T stated for 5150 patients, they always have a sitter. He stated part of a nurse's assessment is to do a primary sweep or safety check of the room. RN T stated the nurse or sitter should do a safety check. RN T stated he remembered when he left the Patient 16, Sitter X was with Patient 16. But when Patient 16 eloped from the ED, Sitter X was not there.</p> <p>During an interview on 9/23/22 at 11:15 a.m, Quality Improvement Coordinator V (QC V) confirmed there was no documentation that indicated a safety check of Patient 16's room was done.</p> <p>Review of Patient 16's ED Provider Notes from Patient 16's second visit to this hospital's ED, dated 5/13/21 at 9:59 p.m., indicated Patient 16 was "covid pos [positive] on 5150 eloped from</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | <p>Continued From page 22</p> <p>ED" and "jumped off 3 floor parking garage and landed in tree." The notes indicated, "19 yo M [year old male] presenting after 30' [foot] fall of building, landed face first. On arrival, bagged with O2 sats [oxygen saturation, level of oxygen in blood, normal levels around 90-100%] in 70s. Intubated [inserted tube through the mouth or nose into the airway to help with breathing] in trauma bay with bilateral breath sounds, persistent sats in 80s. GCS [Glasgow Coma Scale, scoring system to determine level of consciousness and gauge severity of brain injury based on eye response, verbal response, and motor response, scores range from 3 to 15; GCS 3 to 8 classified as severe brain injury] 4, pupils 3 to 2. Blood at face and large chin lac [laceration], agonal respirations [difficulty breathing, gasping] prior to intubation."</p> <p>Review of Patient 16's Trauma - History and Physical, dated 5/13/21 at 10:10 p.m., indicated, "Severe polytrauma [multiple injuries] following fall from fourth floor of a parking structure, COVID-19 positive, CHI (closed head injury) with decreased mental status, unknown period of hypoxia [low oxygen in the tissues] following his fall, complex facial fractures, bilateral orbital fractures (broken bones around eye), bilateral frontal sinuses (hollow space in the bones around the nose), mandible (jaw) and right-sided hard palate (roof of mouth) fractures, consistent with a LeFort III (type of fracture that affects the face), right-sided pneumothorax (a collapsed lung. It occurs when air leaks into the space between the lungs and chest wall), S/P (status post, after) placement of a chest tube, possible aspiration (material entering airway or lungs accidentally), retroperitoneal hematoma with a 2</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/26/2022
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| A 144 | <p>Continued From page 23</p> <p>cm (centimeter, unit of measurement) by 0.6 cm hyper-density next to the left adrenal gland (a small, triangular-shaped gland located on top of the kidney. It produces hormones), possibly consistent with an active extravasation (leakage) of blood; fracture of the left iliac wing (part of pelvis) and severe lactic acidosis (lactic acid build up in the bloodstream. Lactic acid is produced when oxygen levels become low in cells within the areas of the body where metabolism takes place).</p> <p>On the same report, dated 5/13/21, it also indicated the following plans: intubation; fluid resuscitation (replenish body fluid); blood transfusion; admission to Intensive Care Unit (ICU); ear, nose and throat specialist (ENT) consultation for severe facial fractures; interventional radiology (IR) to consult to assess retroperitoneal bleeding; ophthalmology to consult regarding orbital fractures; psychiatry to consult regarding suicidal ideation (SI); orthopedics to consult regarding iliac wing fracture; further radiographs of the right knee; continue tranexamic acid (TXA, medication given to prevent or reduce bleeding); and transfuse as necessary.</p> <p>Review of Patient 16's General Surgery/Trauma Discharge Summary, dated 6/12/21, indicated he had the following operations and procedures performed:</p> <ol style="list-style-type: none"> 1. Left distal radius (wrist) open reduction and internal fixation (ORIF, surgery to fix broken bones) on 5/25/21; 2. Right ORIF of first and third metatarsal (bones in foot) on 5/25/21; 3. Percutaneous endoscopic gastrostomy (PEG, | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 24 a procedure to place tube into stomach to provide nutrition) on 5/27/21; 4. Tracheotomy (a procedure to place tube into the trachea [windpipe] to help a person to breathe), MMF (maxillomandibular fixation, wiring the jaws shut) on 5/27/21.</p> <p>On the same report, dated 6/12/21, it indicated Patient 16 was discharged to another hospital on 6/12/21 for "definitive management of le forte 3 fracture."</p> <p>Review of Patient 16's Physician Discharge Summary, dated 7/8/21, indicated Patient 16 underwent surgery for complex facial repair in another hospital on 6/16/21. Patient 16 was readmitted back to this hospital on 6/28/21 for continuation of treatment. Patient 16 was transferred to the acute rehabilitation unit (ARU) on 7/8/21.</p> <p>Review of Patient 16's Physical Medicine and Rehabilitation Discharge Summary, dated 8/27/21, indicated Patient 16 underwent surgery for removal of maxillary and mandibular hardware on 7/9/21. It also indicated that Patient 16 participated in comprehensive rehabilitation with daily psychiatric management, OT (occupational therapy), PT (physical therapy), SLP (speech therapy), recreational therapy, neuropsychology and 24-hour nursing to address self-care, bed mobility, transfers, wheelchair mobility, balance, pregait and gait activities, neuromuscular facilitation, swallowing, nutrition, communication, cognitive retraining and memory compensatory strategies, bowel and bladder management, safety, behavioral management, equipment evaluation, caregiver training and</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | <p>Continued From page 25 community reentry.</p> <p>Review of a letter addressed to Sitter X, "Subject: Final Disciplinary Action - Termination," dated 10/14/21, indicated Sitter X violated the hospital's administrative policies and procedures, including the policy, "Constant Observation, 1:1 Care, and Enhanced Supervision." The letter indicated it would demonstrate Sitter X's "failure to maintain constant observation that, in part, led to patient harm."</p> <p>Review of the above letter, under the heading, "Failure to Maintain Constant Observation of a Patient, indicated, "When [Sitter X] arrived at room 19, [Sitter X] acquired a Workstation on Wheels (WOW) for documentation purposes and set up the WOW outside of the room with your back to the door and the observation window in the door. [Sitter X] failed to obtain a n95 respirator as part of your personal protective equipment (PPE) prior to starting your assignment. [Sitter X] failed to perform an environment care check of the room prior to sitting for the patient to make sure the room did not have any items that patient [16] could have used to harm himself, staff, or others. During [Sitter X's] constant observation assignment, [Sitter X] had [Sitter X's] back to the patient ... and [Sitter X] failed to chart the patient's status in patient [16]'s Electronic Medical Record (EMR). All of these actions violate County policies. Approximately one hour [6:39 p.m.] into [Sitter X's] constant observation assignment, [Patient 16] pulled out his IV, opened the door to his room, and proceeded to walk in front of [Sitter X] and down the hallway. Despite the importance of [Sitter X's] constant observation role, [Sitter X]</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | <p>Continued From page 26</p> <p>failed to notice that the patient had left the room ... Once [Patient 16] was finished using the public restroom, [Sitter X] escorted him back to room 19, closed the door, moved the WOW in front of the door of the room, abandoned the patient ([Sitter X's] only assignment), and left him unattended. Because [Sitter X was] not present, [Sitter X] could not observe [Patient 16] even though [Patient 16] was a 5150/constant observation patient. Prior to leaving [Patient 16] unattended, [Sitter X] did not hand off [Sitter X's] constant observation responsibilities to another staff member of the ED in direct violation of County policy. As [Sitter X was] not there, [Patient 16] simply opened the door to his room and left for the second time. [Patient 16] then ran out of the ED, left the hospital, ran to an adjacent building, and jumped off a high floor. [Patient 16] returned to [this hospital] as a trauma patient with critical injuries."</p> <p>Review of the hospital's policy, "5150 (or 72 Hour Hold)," dated 1/30/2019, indicated, "A 1:1 sitter is required for any patient held as 5150 DS [danger to self] or DO [danger to others]."</p> <p>Review of the facility's policy, "Suicide/Safety Precautions and Care of the Patient in Non-Behavioral Health Areas," dated 6/24/20 indicated to ensure a safe environment free from any potentially harmful items or environmental conditions. The policy also indicated documentation shall include the means provided by the staff to reduce potential hazards in the patient's environment.</p> <p>Review of the hospital's policy, "Constant Observation, 1:1 Care, and Enhanced</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| A 144 | <p>Continued From page 27 Supervision", dated 6/27/2019, intended for all hospital employees, indicated the following:</p> <p>"Constant Observation (CO): Continuous unbroken observation by appropriate staff from a distance of not more than one arm's length. For agitated and infectious patients, the distance may be increased to two arm lengths or 15 feet for the observer's safety while maintaining a constant view of the patient. CO caregiver (nursing staff) to patient ratio must be 1:1 at all times."</p> <p>"A patient who has expressed suicidal ideation MUST be on CO until a psychiatrist evaluates the patient and determines the patient is no longer a danger to him or herself."</p> <p>"While working a shift as a patient observer/supervisor [sitter], each staff member must ... give report to the patient's nurse before leaving the unit or before performing a task that would prevent them from completing the required supervision ... The staff member must not leave the patient until another staff member is in attendance and a direct report to the relieving staff is given.</p> <p>Review of the hospital's policy, "Chain of Command to Support Safe, Quality Patient Care," dated 11/14/2018 indicated, "Initiating chain of command ensures:</p> <ol style="list-style-type: none"> 1. communication to the appropriate individual to ensure they are aware of the situation; 2. action initiated from the level closest to the event and communication moves through the hierarchy chain as the situation warrants; 3. accountability is maintained when issues are not managed effectively ... " | A 144 | (Please see Attachment A, pg. 8-14) | |
|-------|--|-------|-------------------------------------|--|

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| A 144 | <p>Continued From page 28</p> <p>The policy also indicated, "Every employee has the responsibility to make decisions and take actions that support patient, visitor and staff safety. Employees are to initiate the chain of command when: ... any other situations that may support safe, quality patient care and service ..."</p> <p>3. Review of Patient 16's Patient Care Timeline, dated 5/13/21 indicated Patient 16's EPS Legal Status was "5150" and the reason for 5150 was "Danger to Self; Gravely Disabled."</p> <p>It also indicated on 5/13/21 at 6:55 p.m., RN T documented, "[At] approximately 1847 [6:47 p.m.] Pt [Patient 16] removed IV [intravenous catheter placed in the vein to administer fluids or medication] and exited assigned room and exited ER [emergency room]. Pt not receptive to verbal redirection to return to assigned room. Pt continues to refuse verbal redirection and ran out of ER. 3 ER Staff followed pt past ED CT [computed tomography]. Continued to provide verbal redirection and encouragement to return to ER, pt continues to run and observed pt running toward M building where pt [patient] is longer visible."</p> <p>During a concurrent interview and record review on 9/27/22 at 11:00 a.m. with Registered Nurse L (RN L), the medical record of Patient 44 was reviewed. RN L confirmed Patient 44 was on an involuntary hold and eloped from the locked inpatient psychiatry unit on 10/8/21.</p> <p>During an interview on 9/27/22 at 1:51 p.m., with Registered Nurse WW (RN WW), RN WW stated Patient 44 "was able to obtain the unit keys and</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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| A 144 | <p>Continued From page 29 leave the locked unit with the keys".</p> <p>During a concurrent interview and record review on 9/27/22 at 10:04 a.m. with Registered Nurse L (RN L), the medical record of Patient 43 was reviewed. RN L confirmed Patient 43 was on a 5250 hold [an involuntary hold for up to fourteen days] and eloped from the hospital on 11/27/21.</p> <p>During an interview on 9/27/22 at 4:20 p.m., with Registered Nurse K (RNK), RN K confirmed Patient 43 had eloped from the unit while under constant observation (an increased level of observation and supervision in which continuous one-to-one monitoring techniques are utilized to assure the safety and well-being of an individual patient or others in the patient care environment).</p> <p>During a concurrent interview and record review on 9/29/22 at 10:44 a.m. with Registered Nurse L (RN L), the medical record of Patient 42 was reviewed. RN L confirmed Patient 42 was on a 5150 hold and eloped from the hospital on 1/9/22.</p> <p>Review of Patient 42's physician note, dated 1/9/22, indicated Patient 42 was going to get CT angiogram of neck as well as scalp laceration, when patient stood up and ran out of the emergency department. Police were immediately contacted, and patient was possibly getting into a vehicle, sheriff is aware and actively looking for patient as he is a danger to himself, has an IV (intravenous) in place, and is on a 5150 hold.</p> <p>During a concurrent interview and record review on 9/27/22 at 9:43 a.m. with Registered Nurse M (RN M), the medical record of Patient 41 was</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 144 | <p>Continued From page 30 reviewed. RN M confirmed Patient 41 was on a 5150 hold and eloped from the hospital on 1/17/22.</p> <p>Review of Patient 41's physician note, dated 1/17/ 22, indicated, "Code gray activated this morning after pt [sic] eloped from SICU, ran to CCU, accessed the outdoor patio , scaled the glass and jumped from the second story exterior to the pavement. He was apprehended by law enforcement and is being brought back to the SICU".</p> <p>During a concurrent interview and record review on 9/27/22 at 11:11 a.m. with Registered Nurse Z (RN Z), the medical record of Patient 40 was reviewed. RN Z confirmed Patient 40 was on a 5150 hold and eloped from the hospital on 2/10/22.</p> <p>During an interview on 9/28/22 at 1:02 p.m. with Sitter YY, she stated she was assigned to observe Patient 40 on 2/10/22. Sitter YY stated Patient 40 began to become agitated and Patient 40 stated he was going to leave. Sitter YY stated she did not want to get too close to Patient 40. She stated she was not allowed to physically stop patients. Sitter YY stated Patient 40 left the room and took the elevator down. She stated she and the assigned nurse looked for Patient 40 but could not find him.</p> <p>During a concurrent interview and record review on 9/27/22 at 10:05 a.m. with Registered Nurse I (RN I), the medical record of Patient 39 was reviewed. RN I confirmed Patient 39 was on a 5150 hold and eloped from the locked inpatient psychiatry unit on 5/10/22.</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 | <p>Continued From page 31</p> <p>During an interview with the RN WW on 9/27/22 at 2:35 p.m., she stated there was an ongoing construction in the unit and when the construction worker went out with a staff, Patient 39 went through the open door fast. Patient 39 was escorted back to the unit and put on AWOL (absence without leave) precaution.</p> <p>Review of Patient 39's nursing note dated 5/10/22, indicated, "At around 14:30 (2:30 p.m.) Patient 39 got out of the exit doors and was found running towards the main hospital. She was escorted back to unit with several staff and PSO support".</p> <p>Record review on 9/20/22 at 11:00 a.m. indicated Patient 1 was admitted to the hospital on 8/12/22 for self-inflicted stab wounds to the abdomen and wrist from a suicide attempt. Patient 1 had been placed on a 5150 hold by law enforcement.</p> <p>Further record review indicated Patient 1 continued to have a 1:1 sitter at all times and record review on 9/20/22 at 12:00 p.m of the Death Summary indicated, "On the evening of 8/17/22 at approximately 20:56 (8:56 p.m.) Code Gray was called as the patient was found to be agitated and physically assaulting the sitter in his room ... The RN had to physically pull the sitter from the room for her safety as she was actively being hit by the patient. The patient tried to lunge at staff and the door was closed for the staff safety. The door remained closed for approximately 5 seconds and when it was reopened, the patient was seen back near his bed and appeared to be searching for something while continuing to yell. He then grabbed a chair,</p> | A 144 | (Please see Attachment A, pg. 8-14) | |
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 144 | <p>Continued From page 32</p> <p>lifted it, and broke the window open with the chair. He then proceeded to jump out the window of his room on the 4th story of building E. MD was notified the patient had been pronounced dead on the scene at 21:12 (9:12 p.m.) by EMS [emergency medical services]."</p> <p>During a concurrent interview and record review on 9/27/22 at 3:15 p.m. with Registered Nurse M (RN M), a requested list of patients that eloped from 9/21 to 9/22 was reviewed. The request resulted in 5076 of inpatients and outpatients with the discharge disposition of elopement. RN M stated, "There is no way to indicate what it means by elopement on the patient's discharge disposition."</p> <p>During an interview on 10/3/22 at 12:31 p.m. with the Clinical Risk Prevention Manager (RPM), RPM stated we do not routinely track elopements because they do not fall into the top five categories of event reports.</p> <p>During a review of the hospital's policy and procedure titled, "Occurrence/Event Reporting System" dated June 19, 2015, indicated "An occurrence/event report ...is completed for the purposes of advising Santa Clara Valley Medical Center (SCVMC) and the County of Santa Clara via SCVMC Quality/Risk Management (QI/RM) of an unanticipated or unusual event which results in injury or harm to a patient ...or which creates a risk of injury or harm ..."</p> <p>During a review of the hospital's policy and procedure "Elopement/Missing Patient", dated March 18, 2020, indicated "All reasonable measures will be taken to prevent the elopement</p> | A 144 | (Please see Attachment A, pg. 8-14) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 144 | <p>Continued From page 33</p> <p>of any patient from the hospital". ..." High Risk Patient for Elopement: A patient is at high risk for elopement if he/she is: On a legal hold ..."</p> <p>Review of The Joint Commission's (TJC, (a nationally recognized safety standard organization) "National Patient Safety Goals [NPSG] Effective January 2021 for the Hospital Program," dated 10/28/20 and "National Patient Safety Goals [NPSG] Effective January 2022 for the Hospital Program," dated 10/25/21 indicated that Goal 15 was "The hospital identifies safety risks inherent in its patient population" and NPSG.15.01.01 was to "reduce the risk for suicide." Elements of Performance for NPSG.15.01.01 included the following: "For psychiatric hospitals and psychiatric units in general hospitals: The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide ..." "For nonpsychiatric units in general hospitals: The organization implements procedures to mitigate the risk of suicide for patients at high risk for suicide, such as one-to-one monitoring, removing objects that pose a risk for self-harm if they can be removed without adversely affecting the patient's medical care ..." "Follow written policies and procedures addressing the care of patients identified as at risk for suicide. At a minimum, these should include the following: - Training and competence assessment of staff who care for patients at risk for suicide - Guidelines for reassessment - Monitoring patients who are at high risk for suicide ..." "Monitor implementation and effectiveness of policies and procedures for screening,</p> | A 144 | (Please see Attachment A, pg. 8-14) | |

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| A 144 A 172 | <p>Continued From page 34 assessment, and management of patients at risk for suicide and take action as needed to improve compliance."</p> <p>PATIENT RIGHTS: RESTRAINT OR SECLUSION CFR(s): 482.13(e)(8)(ii)</p> <p>[Unless superseded by State law that is more restrictive,] (ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure Patient 15 was assessed and evaluated for continued use of restraints before renewing the restraint order after 24 hours. This deficient practice had the potential to place Patient 15 at risk for injury.</p> <p>Findings:</p> <p>Review of Patient 15's physician order indicated restraints non-violent /medical continuous for 24 hours from 9/1/22 to 9/4/22. Further review of the order on 9/1/22 under comments indicated, "As evidenced by the following specific behaviors and clinical information: Protect patient from injury when pulling at lines, tubes, indwelling catheter, etc. For renewal, I have assessed the patient and determined the need for restraint is still necessary." From 9/2/22 to 9/4/22, the comments section on the order were missing.</p> | A 144 A 172 | (Please see Attachment A, pg. 8-14) (Please see Attachment A, pg. 14-15) | |

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

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FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 172 | Continued From page 35 During a concurrent interview and record review with the Chief Medical Officer (CMO) on 9/26/22 at 2:20 p.m., CMO reviewed the non-behavioral order set and the comments as above was integrated. CMO stated there might be a technical issue from 9/2/22 to 9/4/22 in which the comments in the order set did not include the renewal statement as above for face to face assessment. CMO stated providers could also write their face to face assessment in their progress notes for renewal of restraints and she would look for other documentation. CMO was not able to provide documentation of Patient 15's face to face assessment for renewal of restraints from 9/2/22 to 9/4/22. Review of the hospital's policy, "Restraint and Seclusion of Patients in Non-Mental-Health Acute Care Settings", dated 6/24/2020, indicated the licensed provider must complete a face to face review of the patient's condition, response to restraints and need for continued restraints and renew or discontinue the restraints every twenty-four hours. | A 172 | (Please see Attachment A, pg. 14-15) | |
| A 174 | PATIENT RIGHTS: RESTRAINT OR SECLUSION CFR(s): 482.13(e)(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure Patient 38 met the criteria for discontinuing restraints according to the hospital's policy and procedure. This deficient | A 174 | (Please see Attachment A, pg. 15-16) | |

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

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FORM APPROVED
OMB NO. 0938-0391

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| A 174 | <p>Continued From page 36</p> <p>practice resulted in inaccurate record in determining the decision to discontinue the restraint.</p> <p>Findings:</p> <p>Review of Patient 38's physician order dated 6/10/22, indicated restraints non-violent/medical continuous for 24 hours.</p> <p>During a concurrent interview and record review with registered nurse I (RN I) on 9/27/22 at 10:05 a.m., Patient 38's non-violent restraints flowsheet indicated restraints were discontinued on 6/11/22 at 6:07 a.m. The discontinuation criteria was left blank on the flow sheet. RN I confirmed she could not find the documentation for discontinuation of Patient 38's restraints.</p> <p>Review of the hospital's policy, "Restraint and Seclusion of Patients in Non-Mental-Health Acute Care Settings", dated 6/24/2020, indicated discontinuation of restraints requires documentation on the nursing flow sheet of the time and either the criteria that patient met for release or the emergency requiring release.</p> | A 174 | (Please see Attachment A, pg. 15-16) | |
| A 263 | <p>QAPI CFR(s): 482.21</p> <p>The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.</p> <p>The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including</p> | A 263 | <p>Please see Attachment A, pg. 16 and please refer to tags: A286 pg. 18-20 A273 pg. 16-17 A315 pg. 21-22 A308 pg. 20 -A084 pg. 2-4</p> | |

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| A 263 | <p>Continued From page 37 those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.</p> <p>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</p> <p>This CONDITION is not met as evidenced by: Based on interview and record review, the hospital failed to carry out its Quality Assessment and Performance Improvement (QAPI) program when the following occurred:</p> <ol style="list-style-type: none"> 1. Failure to perform root cause analyses for two patient-to-patient sexual assaults (refer to A-0286). 2. Failure to perform root cause analysis for one patient elopement and to track patient elopements from the hospital (refer to A-0286). 3. Failure to incorporate relevant data into one quality assessment project (refer to A-0273). 4. Failure to provide adequate resources for QAPI projects and QAPI training (refer to A-0315). 5. Failure to evaluate two contracted services annually (refer to A-0308). <p>These cumulative failures resulted in the hospital's inability to ensure provision of quality care in a safe environment, as required by the Quality Assessment and Performance Improvement Program Condition of Participation.</p> | A 263 | <p>Please see Attachment A, pg. 16 and please refer to tags: A286 pg. 18-20 A273 pg. 16-17 A315 pg. 21-22 A308 pg. 20 -A084 pg. 2-4</p> | |

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| A 273 | <p>DATA COLLECTION & ANALYSIS CFR(s): 482.21(a), (b)(1),(b)(2)(i), (b)(3)</p> <p>(a) Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes ... (2) The hospital must measure, analyze, and track quality indicators ... and other aspects of performance that assess processes of care, hospital service and operations.</p> <p>(b) Program Data (1) The program must incorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions. (2) The hospital must use the data collected to-- (i) Monitor the effectiveness and safety of services and quality of care; and</p> <p>(3) The frequency and detail of data collection must be specified by the hospital's governing body. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to incorporate relevant data into one quality assessment project. This deficient practice had the potential for the hospital to be unaware of the effectiveness of its services.</p> <p>Findings: During an interview on 9/28/22 at 3:24 p.m. with the first Co-Chair of the Critical Care Committee</p> | A 273 | (Please see Attachment A, pg. 16-17) | |

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

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OMB NO. 0938-0391

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| A 273 | Continued From page 39 (MD KK), MD KK stated he reviews Code Blue [term used to describe a hospital patient with cardiac arrest (heart stops beating suddenly) or respiratory arrest (breathing stops or is ineffective)] data monthly. MD KK stated the data he reviews includes the time of day, location of the Code Blue, the heart rhythm, the time to Epinephrine [medication used to treat cardiac arrest], the time to defibrillation [administering electric shock to the heart], the time to return of spontaneous circulation [ROSC, return of effective blood flow], and the disposition of the patient. MD KK stated the Code Blue data is reported at the Critical Care Committee monthly. When asked if reviewing Code Blue data is required of the hospital, MD KK stated he believes it is but he does not know who requires it. MD KK stated he has been collecting Code Blue data for five to seven years. When asked if there was a determination at the start of the project what the data goals or targets should be, MD KK stated no one told him when he started and that he is not sure it was discussed. When asked if anyone asked what the goals or targets of the Code Blue data points are, MD KK stated no one has asked him. MD KK stated the hospital also looks at Targeted Temperature Management (TTM) for cardiac arrest patients. MD KK stated the goal is to maintain euthermia [normal body temperature]. MD KK stated the hospital started the TTM project over five years ago. MD KK stated, when ordering TTM for patients, there are inclusion criteria [guidelines for qualifying patients] and exclusion criteria [guidelines for disqualifying patients]. MD KK stated, for the TTM project, he does not have the number of patients who were qualified to receive TTM based on inclusion criteria. MD KK stated he only | A 273 | (Please see Attachment A, pg. 16-17) | | |

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

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FORM APPROVED
OMB NO. 0938-0391

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| A 273 | <p>Continued From page 40</p> <p>has the number of patients who actually received TTM. MD KK stated he does not have the 2021 data for the TTM project yet. MD KK stated his colleague has not extracted 2021 data from the electronic medical record yet. When asked if data on the length of the resuscitation [medical intervention to restore heartbeat or breathing] was included for the Targeted Temperature Management project, MD KK stated he does not think his colleague looks at that. MD KK stated they look at the patient's initial heart rhythm, the location of the cardiac arrest, and patient outcomes. MD KK stated patient outcomes were the total number of TTM patients, and the number of TTM patients with category 1 brain disability and category 2 brain disability. When asked what changes the hospital made to Targeted Temperature Management, MD KK stated recent research led the hospital to increase the targeted temperature by two degrees. When asked if there was anything from the project data that led to changes in Targeted Temperature Management, MD KK stated no.</p> <p>During a concurrent interview and record review on 9/30/22 at 2:03 p.m. with MD KK and the second Co-Chair of the Critical Care Committee (MD MM), the Critical Care Committee Annual Report 2020, dated November 4th, 2020, was reviewed. The Critical Care Committee Annual Report Summary of Ongoing Activities 2020 included Post Cardiac Arrest Targeted Temperature Management (TTM) Monitor 2020. A slide titled Hypothermia Data (2020) noted 23 total cases divided into three heart rhythm groups. Each group noted the number of patients with each heart rhythm, the location of the cardiac arrest, and how many patients died. A</p> | A 273 | (Please see Attachment A, pg. 16-17) | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 273 | <p>Continued From page 41</p> <p>slide titled Cerebral Performance Categories Scale noted five categories of brain disability. A slide titled Annual TTM Outcomes noted the total number of patients who received TTM and the number of patients with category 1 and category 2 brain disability. MD MM confirmed the Targeted Temperature Management project is a project they use to monitor patient outcomes. MD KK stated he does not have data on the number of patients who met inclusion criteria for TTM compared with the number of patients who actually received it.</p> <p>During an interview on 9/29/22 at 4:23 p.m. with the Quality Improvement Manager (QM NN), QM NN stated she views projects related to patient outcomes as quality improvement projects. QM NN stated the hospital is finally looking at service lines and clinical departments to improve clinical outcome measures. QM NN stated the hospital is not fully there yet. When asked if she would expect to see data collection, data analysis, and decision-making about interventions for outcomes data projects, QM NN stated the hospital is not there yet with their service lines and clinical departments. QM NN stated the service lines and clinical departments should be looking at their data and analyzing it. QM NN stated she is not aware of all Critical Care Committee projects and the reasons for the projects, and that is part of the struggle.</p> <p>During a review of The Joint Commission's R3 Report titled Resuscitation Standards for Hospitals, published June 18, 2021, indicated "... Effective January 1, 2022, new and revised requirements related to resuscitation care [restarting a person's heartbeat or breathing after</p> | A 273 | (Please see Attachment A, pg. 16-17) | |

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| A 273 | Continued From page 42 one or both have stopped] will be applicable to Joint Commission-accredited hospitals ...". The report requires the hospital to collect data on the number and location of cardiac arrests [heart stops beating suddenly], the outcomes of resuscitation, and transfers to a higher level of care. The report also requires the hospital to review cardiac arrest cases and data "... to identify and suggest practice and system improvements in resuscitation performance ...". During an interview on 9/28/22 at 10:35 a.m. with the Hospital Medical Director (MD GG), MD GG confirmed the hospital is accredited by The Joint Commission. During a review of the hospital's policy and procedure titled Performance Improvement Plan, dated June 6, 2000, indicated "... The Medical Staff organization, within each division, as well as the [Hospital's] patient care service departments, share the responsibility for planning, designing, measuring, evaluating and improving the major functions of care service ...". | A 273 | (Please see Attachment A, pg. 16-17) | | |
| A 286 | PATIENT SAFETY CFR(s): 482.21(a), (c)(2), (e)(3) (a) Standard: Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors. (2) The hospital must measure, analyze, and track ...adverse patient events ... (c) Program Activities (2) Performance improvement activities must | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 286 | <p>Continued From page 43</p> <p>track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</p> <p>(e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: ...</p> <p>(3) That clear expectations for safety are established.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to track adverse patient events and formally analyze their causes when</p> <p>1. One sentinel event, Patient 16's elopement [leaving the hospital without permission] while on a 5150 hold [an involuntary hold placed when a patient is a danger to self, others, or gravely disabled], did not undergo a root cause analysis [method used to analyze adverse patient events, which focuses on identifying underlying problems that increase likelihood of errors] and patient elopements from the hospital, including locked units, are not being tracked</p> <p>2. One sentinel event, a patient-to-patient sexual assault event, occurred in the inpatient psychiatry unit and did not undergo a root cause analysis</p> <p>3. One sentinel event, a patient-to-patient sexual assault event, occurred in the psychiatry emergency room and did not undergo a root cause analysis</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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|--------------------|--|---------------|---|----------------------|
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| A 286 | <p>Continued From page 44</p> <p>These deficient practices resulted in the hospital not recognizing issues that potentially contributed to adverse patient events from a systems standpoint, placing the health and safety of patients at risk.</p> <p>Findings:</p> <p>During a review of the hospital's policy and procedure titled Patient Safety Plan, undated, indicated "... The purpose of the Patient Safety Plan (The Plan) is to improve patient safety, outcomes, and reduce preventable patient safety events ...". The policy noted the Patient Safety Committee is responsible for "... Reviewing reports regarding patient safety events, including potential or no-harm errors to hazardous conditions and sentinel events ... Monitoring the implementation of corrective actions for patient safety events ... Making recommendations to eliminate or mitigate future patient safety events ... Assuring a reliable process for analyses, including, but not limited to, root cause analyses of patient safety events ...". The policy defined Sentinel Event as "... An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof ...". The policy defined Patient Safety Events as including "... all adverse events or potential adverse events that are determined to be preventable ... these events include those deemed reportable by the California Center for Medicare and Medicaid Services (CMS), the California Health and Safety Code, and The Joint Commission (TJC) ...".</p> | A 286 | (Please see Attachment A, pg. 18-20) | |
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/26/2022
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| A 286 | <p>Continued From page 45</p> <p>During a review of the hospital's policy and procedure titled Reportable Adverse and Sentinel Events, dated June 19, 2015, indicated the hospital "... shall conduct an investigation and as appropriate, a root cause analysis (RCA) of reportable adverse events as defined by CMS and [State Survey Agency], and TJC sentinel events to identify causal factors and support the development and implementation of strategies that will reduce the risk of similar events recurring ...". The policy noted "... Medical Director or designee ... Identifies event as reportable adverse or sentinel event. Recommends course and level of review: Sentinel event root cause analysis ...".</p> <p>During an interview on 9/22/22 at 1:40 p.m. with the Hospital Medical Director (MD GG), MD GG stated both in-progress and completed root cause analyses are discussed at Patient Safety Committee. MD GG stated the Quality Department conducts the root cause analyses.</p> <p>During an interview on 9/22/22 at 9:54 a.m. with the Hospital Medical Director (MD GG), MD GG stated Patient Safety Committee information is communicated up to the hospital's Medical Leadership Council, then to the Enterprise Medical Executive Committee, and then to the Governing Body.</p> <p>During an interview and record review on 9/21/22 at 8:44 a.m. with the Interim Enterprise Quality Manager (QM FF), the QM FF provided a list of root cause analyses (RCA) for the past twelve months. There were four patient events on the list. The survey team requested a list of root cause analyses for the past eighteen months.</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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OMB NO. 0938-0391

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| A 286 | <p>Continued From page 46</p> <p>During an interview and record review on 9/22/22 at 12:08 p.m. with the Interim Enterprise Quality Manager (QM FF), the QM FF stated the list of RCAs for the past eighteen months was the same as the list for the past twelve months. The list of RCAs for the past eighteen months did not include the incident involving Patient 16, who eloped from the emergency room while on a 5150 hold in May 2021.</p> <p>During a review of a sample of Facility Reported Incidents reported to the State Survey Agency, dated 9/27/22, indicated there were two patient-to-patient sexual assaults that occurred in the hospital in the past twelve months and were previously investigated by the State Survey Agency.</p> <p>1. During a review of Patient 16's medical record, indicated Patient 16 was seen at an outside hospital's emergency department on 5/12/2021 for acting strange and discussing suicide. Patient 16 was placed on a 5150 hold for danger to self and gravely disabled. Patient 16 eloped from the outside hospital's emergency department, the security guard was unable to catch up and Patient 16 got away. Police were called, and the police and ambulance staff subsequently found Patient 16 down the street. Patient 16 was transferred to this hospital's psychiatry emergency room on 5/13/2021 and then to this hospital's main emergency department on 5/13/2021 for evaluation. A security guard report, dated 05/17/2021, indicated a security guard escorted Patient 16 on 5/13/2021 from the psychiatry emergency room to the main</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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| A 286 | <p>Continued From page 47</p> <p>emergency department (ED). The security guard noted the psychiatry emergency room staff "... informed me that the patient was a flight risk ..." and upon arrival to the main ED, the security guard "... informed the ER staff [Registered Nurse T] that [Patient 16] was a flight risk and could possibly try to elope. Staff put the patient in the room and then assigned a sitter for the patient no restraints or medication was given at that time ...". In his ED Notes, dated 5/13/2021 at 6:55 p.m., Registered Nurse T noted at approximately 6:47 p.m., Patient 16 ran out of the ED, followed by three ED staff members. Patient 16 was observed running toward a different hospital building until he was no longer visible. Registered Nurse T noted at 6:49 p.m., security was contacted, the charge nurse was notified, and the ED physician was notified.</p> <p>A security guard report, undated, indicated the security guard received a call on May 13, 2021 from the emergency department staff that a 5150 patient ran away from the ED. The security guard stated he dispatched another security guard to respond to the 5150 patient elopement. The security guard stated he received several phone calls about the 5150 patient running through a hospital building lobby. The security guard report indicated several security guards searched on the public streets for Patient 16. The security guard observed Patient 16 walking up the stairs to the top floor of a college's parking structure. The sheriffs arrived at the parking structure and the security guards departed.</p> <p>In his ED Provider Notes, dated 5/13/2021 at 9:59 p.m., the emergency department physician noted Patient 16 jumped off a three-floor parking</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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| A 286 | <p>Continued From page 48</p> <p>garage and landed in a tree. In his Trauma - History and Physical note, dated 5/13/2021 at 8:44 p.m., the surgeon noted Patient 16 had severe trauma following a fall from the fourth story of a parking structure, including closed head injury with decreased mental status, significant and complex facial fractures, and a fracture of the left iliac wing [pelvic bone]. The surgeon noted Patient 16 had an unknown period of hypoxia [decreased oxygen supply] after his fall. In his General Surgery/Trauma Discharge Summary, dated 5/27/2021 at 3:48 p.m., the surgeon noted Patient 16 was being transferred to another hospital for surgical management of one of his facial fractures. The surgeon noted Patient 16 had undergone multiple surgeries, including surgery to repair a left wrist fracture and surgery to repair right foot fractures. The surgeon noted Patient 16 had severe traumatic brain injury.</p> <p>During an interview on 9/22/22 at 3:36 p.m. with the Director of Nursing for Critical Care (DNCC) and the Emergency Department Nurse Manager (NM S), the DNCC stated she oversees the emergency department (ED). The DNCC stated patients on a 5150 hold are placed in specific scrubs and assigned a sitter. The DNCC stated the sitter is responsible for providing constant observation within arms reach, facing the patient. The DNCC stated the ratio is one sitter for every 5150 patient. For Patient 16, the DNCC stated the sitter was supposed to visualize Patient 16 through the window of the closed door since Patient 16 was COVID-19-positive [a viral illness that can cause difficulty breathing]. The DNCC stated Patient 16 was inside the ED room and the sitter was outside the room. The DNCC</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 49</p> <p>stated Registered Nurse T was the primary nurse and Registered Nurse U was assisting in the care of Patient 16. The DNCC stated, for Patient 16, the sitter was not paying attention and had his back to the patient's door. The DNCC stated Patient 16 left the ED room without the sitter noticing. NM S stated a janitor noticed there was no patient in the room and asked if the room was ready to clean. NM S stated the janitor spoke with Registered Nurse U. NM S stated Registered Nurse U and the sitter then looked for Patient 16, found Patient 16 in the bathroom and walked him back to the ED room. The DNCC stated the sitter then walked away from Patient 16's ED room to look for personal protective equipment. The DNCC stated Patient 16 then opened the door and ran into Registered Nurse U. The DNCC stated Registered Nurse U tried to redirect Patient 16, but Patient 16 left the ED and started to run. The DNCC stated Patient 16's ED room was located next to a set of doors, and that Patient 16 had to exit two sets of doors to get into the main hospital before exiting to the street. The DNCC stated hospital staff and security ran after Patient 16, and the sheriff was called. The DNCC stated Patient 16 went across the street and up a parking structure. The DNCC stated Patient 16 fell off the parking structure and landed in a tree, and was brought back to the hospital ED by ambulance as a trauma patient.</p> <p>During a concurrent interview and record review on 9/26/22 at 12:00 p.m. with the DNCC, NM S, Registered Nurse T (RN T) and Registered Nurse U (RN U), ED security video footage of Patient 16 and a map of the ED were reviewed. The DNCC stated the video timestamps were accurate. The DNCC stated ED staff is assigned</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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| A 286 | <p>Continued From page 50</p> <p>to a "team" of four ED rooms in close proximity. RN T stated patient assignments would be for those four ED rooms only. The DNCC stated each team has a specific nursing station. RN T and RN U stated they use the team area to make telephone calls and complete patient charting. RN U stated the only reason nurses step out of the team area is to send and receive labs or medications. The map showed the location of Patient 16's ED room, the nursing station, and the bathroom. The bathroom was located directly across the hallway from the nursing station.</p> <p>For Video One, the footage showed an emergency department hallway on 5/13/2021 at 6:39 p.m. The DNCC stated the sitter was sitting with his back to Patient 16's room and the door was closed. RN U was observed speaking with a female staff member in the middle of the hallway. RN U stated he was speaking with another ED nurse. On 5/13/2021 at 6:40 p.m., Patient 16 walked out of his ED room, passing in front of the sitter and by RN U in the hallway before walking off camera. The sitter was sitting at a computer and had his back to Patient 16's room. Neither the sitter nor RN U appeared to notice Patient 16 walk by. RN U stated he spoke with a janitorial services staff member on 5/13/2021 at 6:40 p.m. The janitorial staff member and RN U pointed to Patient 16's ED room. The sitter looked into Patient 16's ED room. The sitter stood up from his computer and appeared to speak to RN U. The sitter and RN U stood next to each other in the hallway, looking into Patient 16's ED room. The sitter walked off camera while RN U looked in Patient 16's ED room. RN T went on and off camera. RN U looked down the hallway and then entered, exited, and re-entered a different ED</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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| A 286 | <p>Continued From page 51</p> <p>room. RN U then exited the other ED room and stood in the hallway next to the nursing station. On 5/13/2021 at 6:42 p.m., the sitter walked Patient 16 back through the hallway to his ED room.</p> <p>When asked what clothing Patient 16 was wearing, RN U stated Patient 16 was wearing distinctive 5150 scrubs. RN T stated the scrubs were a very specific teal color so hospital staff can identify 5150 patients. RN U stated Patient 16 was given these 5150 scrubs in the psychiatry emergency room before he was transferred to the main ED. RN U stated the psychiatry emergency room and main ED use the same color for 5150 scrubs. RN T stated, if hospital staff saw this color of scrubs, it would be noticeable to them that the patient was a 5150 patient. When asked why he did not notice Patient 16 walking by him in distinctive 5150 scrubs, RN U stated he was in conversation with another staff member at that time and did not have his glasses on. RN T stated he was at the nursing station and did not notice Patient 16 walk by. NM S estimated the hallway from Patient 16's ED room to the bathroom was maybe twelve feet long. RN T and RN U stated the only time a 5150 patient is supposed to leave his or her ED room is for procedures or to use the bathroom, but the patient is supposed to be accompanied by hospital staff at all times. RN T stated he was not informed Patient 16 went to the bathroom unsupervised. RN U stated, when he looked into Patient 16's ED room, he did notice Patient 16 was gone. RN U confirmed the sitter was standing next to him when he looked into Patient 16's ED room. When asked if he found it odd that the sitter was standing next to him and Patient 16</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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| A 286 | <p>Continued From page 52</p> <p>was missing, RN U stated he told the sitter to go locate Patient 16. RN U stated he told the sitter that the sitter had to be with Patient 16 all the time. When asked if he escalated the information about the sitter being unaware Patient 16 was missing, RN U stated they kept that information to themselves. RN T stated he was not aware of that information. When asked if she would have expected that information to be relayed to the charge nurse, NM S said she guessed she wouldn't because Patient 16 was found. When asked what staff is supposed to do when they notice a patient is missing, RN U stated they are supposed to notify security, the physician, sheriffs, and the charge nurse. When asked if security, the physician, sheriffs, and the charge nurse were notified when Patient 16 was missing, RN U stated no because they found Patient 16.</p> <p>For Video Two, the footage showed an emergency department hallway on 5/13/2021 at 6:43 p.m. The DNCC stated the sitter placed Patient 16 back in his ED room. The sitter closed the door. RN U was standing in the middle of the hallway by the nursing station. The sitter appeared to speak with a staff member in the hallway, then walked down the hallway past RN U and off camera. On 5/13/2021 at 6:44 p.m., the sitter walked back on camera and past RN U. The sitter appeared to place something on his computer before walking off camera again. RN U entered and exited a different ED room. On 5/13/2021 at 6:44 p.m., Patient 16 opened his door, left his room and stood in the hallway with RN U. Patient 16 appeared to be speaking with RN U. Patient 16 walked to a set of double doors and left. Hospital staff ran after Patient 16. RN U stated he did not notice the sitter walking away</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 286 | <p>Continued From page 53</p> <p>from Patient 16's room. RN U stated he relies on sitters to tell him if they need to walk away. RN T stated he was at the nursing station. RN T stated it is possible to see Patient 16's room from the nursing station. RN T stated he did not see the sitter leave Patient 16's room and walk down the hallway. RN U stated he did not notice the sitter leave and walk down the hallway. When asked who is allowed to give direction to sitters, RN U stated the charge nurse. NM S stated, if a sitter leaves his station, the bedside nurse is allowed to give direction to the sitter.</p> <p>During an interview on 9/22/22 at 3:36 p.m. with the Director of Nursing for Critical Care (DNCC) and the Emergency Department Nurse Manager (NM S), NM S stated she called the DNCC the day of the patient event. The DNCC stated she and NM S started an internal investigation of the event. The DNCC stated the investigation pointed more to a personnel issue with the sitter, because the hospital had systems in place to guide the sitters. The DNCC stated this sitter disregarded hospital policies. When asked what changes were made in the hospital after this patient event, the DNCC stated they terminated the sitter and started staff re-education immediately. NM S stated the education involved discussion about constant observation and restraints. NM S stated it was verbal education only, and there was no test after the staff re-education. The DNCC stated it was a refresher, because ED staff are given this information on hire and annually. When asked if the ED changed anything as a result of this patient elopement, NM S stated no because their systems are in place and are pretty good.</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 54</p> <p>During an interview on 9/30/22 at 3:01 p.m. with the Clinical Risk Prevention Manager (RPM), the RPM stated there was no root cause analysis done for Patient 16's event. The RPM stated the hospital reviewed security video footage and saw the sitter walk away from his post without asking other staff to watch Patient 16. The RPM stated the hospital dismissed the sitter and felt this was an individual employee issue. The RPM stated the hospital did not feel a root cause analysis was needed. The RPM confirmed the hospital is accredited by The Joint Commission and abides by The Joint Commission's definition of sentinel events. The RPM confirmed sentinel events require a root cause analysis.</p> <p>During an interview on 9/28/22 at 10:35 a.m. with the Hospital Medical Director (MD GG), MD GG confirmed the hospital is accredited by The Joint Commission. MD GG stated the hospital should abide by what The Joint Commission considers to be a Sentinel Event. MD GG stated he, the Clinical Risk Prevention Manager, and the Director of Quality and Safety participate in determining which patient events require a root cause analysis.</p> <p>During a concurrent interview and record review on 10/3/22 at 10:33 a.m. with the RPM, Hospital Medical Director (MD GG), and the Director of Quality and Safety (DQS), The Joint Commission presentation titled Most Commonly Reviewed Sentinel Event Types updated 02/01/21 was reviewed. The presentation indicated "... An event is also considered sentinel if it is one of the following ... Any elopement (that is, unauthorized departure) of a patient from a staffed around the-clock care setting (including the ED), leading</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 55</p> <p>to death, permanent harm, or severe temporary harm to the patient ...". The RPM confirmed the hospital is accredited by The Joint Commission and follows The Joint Commission's definition of sentinel events. When asked if Patient 16's elopement met The Joint Commission criteria for a sentinel event, the RPM stated yes. The RPM confirmed there was no root cause analysis for Patient 16's elopement. The RPM stated they determined staffing was adequate and the patient was on constant observation precautions, so they concluded a root cause analysis was not needed. The RPM stated they reviewed security video footage and saw the sitter walk away. MD GG stated he and the RPM discussed that they felt this was a personnel issue rather than a systems issue.</p> <p>During an interview on 10/3/22 at 12:50 p.m. with the RPM, MD GG, and DQS, when asked if they were aware Patient 16 passed by the sitter and staff in the hallway while dressed in distinctive 5150 scrubs and no staff noticed Patient 16 walk by unaccompanied to the bathroom, the RPM and MD GG stated this was not mentioned to them. When asked if, when they reviewed Patient 16's elopement, they considered whether there should be staff coming from other areas of the hospital to help look for the patient or to help communicate with the patient after he eloped from the ED, the RPM stated she would have to check to see if hospital staff runs to patient elopements in the ED.</p> <p>During a review of the hospital's policy and procedure titled Elopement/Missing Patient, dated March 18, 2020, indicated "... Upon notification or discovery of a missing/absent</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 56</p> <p>patient in department, immediately ... Call Sheriff's Dispatch Center ... Notify [Hospital] Protective Services Officer and the Nursing Shift Supervisor ... Notify immediate supervisor, page overhead for the patient to return to the patient care area, and initiate a search of the immediate area ... If patient is not found within 10 minutes, notify Hospital Operator to overhead page "Code Green" with description of patient and location last seen ... Upon hearing "Code Green," all available hospital personnel will immediately stop all non-critical work and cover all exits, stairs, and elevators ... Widen the search to include the entire facility if the patient cannot be located and any of the following are concerns ... is under a 5150/72-Hour Hold ...".</p> <p>During an interview on 10/3/22 at 3:04 p.m. with the Quality Improvement Coordinator GG (QC GG), the QC GG stated the main emergency department does not follow the hospital's Code Green policy because it has its own process to contact security.</p> <p>During an interview on 10/3/22 at 12:50 p.m. with the RPM, MD GG, and DQS, the RPM stated Patient 16's elopement did meet The Joint Commission criteria for a sentinel event. The RPM stated they really thought it was a personnel issue, and that the survey team shared information about the distinctive 5150 scrubs they were not aware of.</p> <p>During an interview on 10/3/22 at 3:59 p.m. with the RPM, the RPM stated they were not aware that Registered Nurse U did not inform the charge nurse or his chain of command when Registered Nurse U and the sitter noticed</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 57</p> <p>together that Patient 16 was missing, even though the sitter was supposed to be constantly observing the patient. The RPM stated they were following up again with the Emergency Department Nurse Manager.</p> <p>During an interview on 9/22/22 at 3:36 p.m. with the DNCC and NM S, the DNCC stated she does not track elopements from the ED.</p> <p>During an interview on 10/3/22 at 12:50 p.m. with the RPM, MD GG, and DQS, the RPM stated the hospital does not track patient elopements from the emergency department or the inpatient units on a routine basis. The RPM stated if they receive an electronic event report of a patient elopement, they see if this type of event happened elsewhere in the hospital.</p> <p>During a concurrent interview and record review on 9/26/22 at 3:21 p.m. with the DQS, the DQS stated, if patient elopements are not reported through the hospital's electronic reporting system, hospital departments can track patient elopements if they ask for medical record coding data. The DQS provided a list titled [Hospital] Patient Elopement: 9/2021 - 9/2022. The DQS stated the list was created from electronic patient event reports. There were five patient names on the list. The DQS stated this list did not include patients on a 5150 hold who eloped. The survey team requested the list of patient elopements including 5150 patients from 9/2021 to 9/2022.</p> <p>During a review of the hospital's High Risk Patient Elopement: 9/2021 - 9/2022, indicated there were fourteen patients on the list, including Patients 39, 40, 41, 42, 43, and 44.</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | Continued From page 58 During a concurrent interview and record review on 9/27/22 at 10:05 a.m. with Registered Nurse I (RN I), the medical record of Patient 39 was reviewed. RN I confirmed Patient 39 was on a 5150 hold and eloped from the locked inpatient psychiatry unit on 5/10/22. During a concurrent interview and record review on 9/27/22 at 11:11 a.m. with Registered Nurse Z (RN Z), the medical record of Patient 40 was reviewed. RN Z confirmed Patient 40 was on a 5150 hold and eloped from the hospital on 2/10/22. During a concurrent interview and record review on 9/27/22 at 9:43 a.m. with Registered Nurse M (RN M), the medical record of Patient 41 was reviewed. RN M confirmed Patient 41 was on a 5150 hold and eloped from the hospital on 1/17/22. During a concurrent interview and record review on 9/29/22 at 10:44 a.m. with Registered Nurse L (RN L), the medical record of Patient 42 was reviewed. RN L confirmed Patient 42 was on a 5150 hold and eloped from the hospital on 1/9/22. During a concurrent interview and record review on 9/27/22 at 10:04 a.m. with Registered Nurse L (RN L), the medical record of Patient 43 was reviewed. RN L confirmed Patient 43 was on a 5250 hold [an involuntary hold for up to fourteen days] and eloped from the hospital on 11/27/21. During a concurrent interview and record review on 9/27/22 at 11:00 a.m. with Registered Nurse L | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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FORM APPROVED
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| A 286 | Continued From page 59 (RN L), the medical record of Patient 44 was reviewed. RN L confirmed Patient 44 was on an involuntary hold and eloped from the locked inpatient psychiatry unit on 10/8/21. 2. During a concurrent interview and record review on 9/30/22 at 3:01 p.m. with the Clinical Risk Prevention Manager (RPM), the medical records of the female patient and male patient involved in a patient-to-patient sexual assault event in the inpatient psychiatry unit were reviewed. The female patient was a 30 year old female admitted to the inpatient psychiatry unit for aggression. The male patient was a 57 year old male admitted to the inpatient psychiatry unit for being a danger to self, danger to others, and grave disability. A registered nurse note, dated 12/19/2021 at 8:41 p.m., indicated "... At around 1730, writer saw male patient ... put his hand inside [female patient's] pants, male patient was standing behind her in the dayroom. Writer immediately intervned and separated them, writer attempted to asked [sic] patient what happened but she won't talk ...". A physician note, dated 12/22/2021 at 12:45 p.m., indicated the female patient was "... repeatedly refusing exam after found to have been sexually assaulted a couple of days ago ...". The male patient was discharged to jail. When asked if this was a verified sexual assault incident, the RPM stated yes because the male patient acted without consent. The RPM stated there was no root cause analysis done for this patient-to-patient sexual assault event. The RPM stated this event did not rise to the level of a root cause analysis based on patient harm score, and that the hospital reported the event to the State | A 286 | (Please see Attachment A, pg. 18-20) | | |

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

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| A 286 | <p>Continued From page 60</p> <p>Survey Agency as an unusual occurrence. The RPM confirmed the hospital is accredited by The Joint Commission and abides by The Joint Commission's definition of sentinel events. The RPM confirmed sentinel events require a root cause analysis.</p> <p>During an interview on 9/28/22 at 10:35 a.m. with the Hospital Medical Director (MD GG), MD GG confirmed the hospital is accredited by The Joint Commission. MD GG stated the hospital should abide by what The Joint Commission considers to be a Sentinel Event. MD GG stated he, the Clinical Risk Prevention Manager, and the Director of Quality and Safety participate in determining which patient events require a root cause analysis.</p> <p>During a concurrent interview and record review on 10/3/22 at 10:33 a.m. with the RPM, MD GG, and the Director of Quality and Safety (DQS), The Joint Commission Sentinel Events policy from July 2021 was reviewed. The Joint Commission Sentinel Events policy from July 2021, indicated "... An event is also considered sentinel if it is one of the following ... Sexual abuse/assault of any patient while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization ...". The policy also noted "... Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact including oral, vaginal, or anal penetration or fondling of the individual's sex organ(s) by another individual. One or more of the following must be present to determine that it is a sentinel event ... Any staff-witnessed sexual contact as described</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 61 above ... ". MD GG and DQS reviewed the medical records of the female patient and male patient. The RPM confirmed this was a sexual assault event. The RPM confirmed the hospital is accredited by The Joint Commission and follows The Joint Commission's definition of sentinel events. When asked who decided this patient-to-patient sexual assault event did not require a root cause analysis, the RPM stated when they reviewed this event, they did not feel it met the definition of a sentinel event.</p> <p>3. During a concurrent interview and record review on 9/30/22 at 3:01 p.m. with the Clinical Risk Prevention Manager (RPM), the medical records of the female patient and male patient involved in a patient-to-patient sexual assault event in the psychiatry emergency room were reviewed. The female patient was a 20 year old female seen in the psychiatry emergency room for feeling like she wanted to kill herself. The male patient was a 32 year old male seen in the psychiatry emergency room for mumbling. A registered nurse note, dated 1/8/2022 at 5:15 p.m., indicated "... staff reported witnessing a male peer touched [sic] the client on her behind. This writer interviewed [female patient] and verbalized she was touched. When asked where, she pointed and touched her behind with both of her hands. [Female patient] wanted to press charges ...". A registered nurse note, dated 1/9/2022 at 10:00 a.m., indicated "... Another patient touched [female patient] inappropriately " in my butt" ...". The RPM confirmed this patient-to-patient sexual assault event was witnessed by hospital staff. The RPM confirmed hospital staff witnessed the male patient touching</p> | A 286 | (Please see Attachment A, pg. 18-20) | |

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

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| A 286 | <p>Continued From page 62</p> <p>the female patient on her behind. When asked if this was a verified sexual assault incident, the RPM stated yes because the incident was witnessed and the female patient confirmed the incident occurred. When asked if she has a definition she uses for sexual assault, the RPM stated any unwanted touching. The RPM stated the male patient was discharged to jail. The RPM stated there was no root cause analysis done for this patient-to-patient sexual assault event. The RPM confirmed the hospital is accredited by The Joint Commission and abides by The Joint Commission's definition of sentinel events. The RPM confirmed sentinel events require a root cause analysis.</p> <p>During an interview on 9/28/22 at 10:35 a.m. with the Hospital Medical Director (MD GG), MD GG confirmed the hospital is accredited by The Joint Commission. MD GG stated the hospital should abide by what The Joint Commission considers to be a Sentinel Event. MD GG stated he, the Clinical Risk Prevention Manager, and the Director of Quality and Safety participate in determining which patient events require a root cause analysis.</p> <p>During a concurrent interview and record review on 10/3/22 at 10:33 a.m. with the RPM, MD GG, and the Director of Quality and Safety (DQS), The Joint Commission Sentinel Events policy from July 2021 was reviewed. The Joint Commission Sentinel Events policy from July 2021, indicated "... An event is also considered sentinel if it is one of the following ... Sexual abuse/assault of any patient while receiving care, treatment, and services while on site at the organization/facility or while under the</p> | A 286 | (Please see Attachment A, pg. 18-20) | | |

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| A 286 | Continued From page 63 supervision/care of the organization ...". The policy also noted "... Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact including oral, vaginal, or anal penetration or fondling of the individual's sex organ(s) by another individual. One or more of the following must be present to determine that it is a sentinel event ... Any staff-witnessed sexual contact as described above ... ". MD GG and DQS reviewed the medical records of the female patient and male patient. The RPM confirmed this was a sexual assault event. The RPM confirmed the hospital is accredited by The Joint Commission and follows The Joint Commission's definition of sentinel events. When asked who decided this patient-to-patient sexual assault event did not require a root cause analysis, the RPM stated when they reviewed this event, they did not feel it met the definition of a sentinel event. | A 286 | (Please see Attachment A, pg. 18-20) | |
| A 308 | QAPI GOVERNING BODY, STANDARD TAG CFR(s): 482.21 ... The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement) ... The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to evaluate two contracted services annually. This deficient practice had the potential for the governing body to be unaware of whether contracted services were provided in a | A 308 | Please see Attachment A, pg. 21 and please refer to tag: A084 pg. 2-4 | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 308 | <p>Continued From page 64 safe and effective manner to patients.</p> <p>Findings:</p> <p>During an interview on 9/26/22 at 10:31 a.m. with the Chief Operating Officer (COO), the COO stated every contract is supposed to undergo a performance review annually at minimum.</p> <p>During a review of the hospital's policy and procedure titled Policies on Soliciting and Contracting, revised 5-24-22, indicated, "... Monitoring, administration and evaluation of County contracts are essential ... to ensuring that the County receives the goods and/or services for which it contracts ... Agencies/Departments are required to develop performance standards and implement a process that incorporates monitoring, administration and evaluation of contracts ... Agencies/Departments must also document their performance evaluations of contractors ... These performance evaluations may be used by Agencies/Departments to evaluate the propriety of entering into contract extensions or future agreements with the same contractor. The Board or Board Committees may also request copies of evaluations from time to time ...".</p> <p>During a review of the hospital's governing body bylaws, dated December 15, 2020, indicated the Chief Executive Officer was responsible for maintaining a list of all contracted services and providing the Governing Body with "... information that the services performed under contracts are provided in a safe and effective manner ...".</p> | A 308 | Please see Attachment A, pg. 21 and please refer to tag: A084 pg. 2-4 | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 308 | <p>Continued From page 65</p> <p>During an interview on 9/27/22 at 9:45 a.m. with the COO and the Director of Contracts (DCTS), the COO stated the hospital's Chief Executive Officer (CEO) has the authority to review the performance of all contracts to see if the contracted services are performed in a safe and effective manner.</p> <p>During a review of the hospital's medical gas contract indicated it is effective from December 1, 2020 to November 30, 2025. During a review of the hospital's contract to purchase C-arm [a mobile device used to take images during procedures] diagnostic imaging equipment, service, and maintenance indicated it is effective from July 1, 2020 to June 30, 2025.</p> <p>During an interview on 9/27/22 at 4:20 p.m. with the COO, the COO confirmed there was no medical gas contract evaluation and no C-arm contract evaluation for 2021 to 2022.</p> <p>During an interview on 9/27/22 at 4:59 p.m. with the COO, the COO confirmed there was no medical gas contract evaluation and no C-arm contract evaluation for 2020 to 2021. When asked if the hospital was supposed to have completed contract evaluations for the medical gas contract and the C-ARM contract, the COO stated yes because the evaluations were supposed to be filled out annually.</p> <p>During a concurrent interview and record review on 9/30/22 at 11:09 a.m. with the COO, Chief Procurement Officer for the county, Supervisor of Respiratory Care Services (SRC OO), and the Operating Room Director (MD PP), the hospital's</p> | A 308 | Please see Attachment A, pg. 21 and please refer to tag: A084 pg. 2-4 | |

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

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| A 308 | <p>Continued From page 66</p> <p>policy and procedure titled Policies on Soliciting and Contracting, revised 5-24-22, was reviewed. The COO confirmed that the policy's statement "...Agencies/Departments must also document their performance evaluations of contractors ..." meant the hospital is expected to fill out the Contract Monitoring Tool for all contracts annually. The COO stated the hospital does not have completed Contract Monitoring Tool forms for the medical gas contract and the C-arm contract. The SRC OO stated he does not fill out any evaluation forms on how well the medical gas contractor is doing. The SRC OO stated there was no formal evaluation process for the medical gas contract. The SRC OO stated the Enterprise Director of Ancillary Services would be the staff member communicating with the CEO about the hospital's satisfaction with the medical gas contract. When asked how often the Enterprise Director of Ancillary Services reports to the CEO about the medical gas contract, the SRC OO stated he did not know. The SRC OO stated he would think there were no reports to the CEO because he has never had to escalate any issues. MD PP stated there was no formal process for evaluating the C-arm contract. MD PP stated she has regular meetings with the CEO about contracts, but stated she does not have a formal tracking system showing she has discussed all of her contracts with the CEO.</p> <p>During a review of the hospital's Contract Monitoring Tool, undated, indicated the tool asked, "... Did the Contractor meet the objectives/scope of services in a satisfactory manner? Timeliness? Quality of Care? Availability? ... Did you or anyone else encounter any issues/problems with the quality of services</p> | A 308 | Please see Attachment A, pg. 21 and please refer to tag: A084 pg. 2-4 | |

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| A 308 A 315 | <p>Continued From page 67 provided? ... Were county required compliance and performance standards met? ... Are there any other concerns with this Contractor? ...".</p> <p>PROVIDING ADEQUATE RESOURCES CFR(s): 482.21(e)(4)</p> <p>[The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:]</p> <p>(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to provide adequate resources for departmental quality assessment projects. This deficient practice resulted in one clinical service line not having enough staff or training to conduct quality assessment projects.</p> <p>Findings:</p> <p>During an interview on 9/28/22 at 3:24 p.m. with the first Co-Chair of the Critical Care Committee (MD KK), MD KK stated he reviews Code Blue [term used to describe a hospital patient with cardiac arrest (heart stops beating suddenly) or respiratory arrest (breathing stops or is ineffective)] data monthly. MD KK stated the data</p> | A 308 A 315 | <p>Please see Attachment A, pg. 21 and please refer to tag: A084 pg. 2-4</p> <p>(Please see Attachment A, pg. 21-22)</p> | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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| A 315 | Continued From page 68 he reviews includes the time of day, location of the Code Blue, the heart rhythm, the time to Epinephrine [medication used to treat cardiac arrest], the time to defibrillation [administering electric shock to the heart], the time to return of spontaneous circulation [ROSC, return of effective blood flow], and the disposition of the patient. When asked if reviewing Code Blue data is required of the hospital, MD KK stated he believes it is but he does not know who requires it. MD KK stated he has been collecting Code Blue data for five to seven years. When asked if there was a determination at the start of the project what the data goals or targets should be, MD KK stated no one told him when he started and that he is not sure it was discussed. When asked if anyone asked what the goals or targets of the Code Blue data points are, MD KK stated no one has asked him. MD KK stated the hospital also looks at Targeted Temperature Management (TTM) for cardiac arrest patients. MD KK stated the goal is to maintain euthermia [normal body temperature]. MD KK stated the hospital started the TTM project over five years ago. MD KK stated, when ordering TTM for patients, there are inclusion and exclusion criteria [guidelines for qualifying or disqualifying patients]. MD KK stated, for the TTM project, he does not have the number of patients who were qualified to receive TTM based on inclusion criteria. MD KK stated he only has the number of patients who actually received TTM. MD KK stated he does not have the 2021 data for the TTM project yet. MD KK stated his colleague has not extracted 2021 data from the electronic medical record yet. When asked if data on the length of the resuscitation [medical intervention to restore heartbeat or breathing] was included for the Targeted | A 315 | (Please see Attachment A, pg. 21-22) | | |

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| A 315 | <p>Continued From page 69</p> <p>Temperature Management project, MD KK stated he does not think his colleague looks at that. MD KK stated they look at the patient's initial heart rhythm, the location of the cardiac arrest, and patient outcomes. MD KK stated he does not have a committee to deal with this data, and he has a lot of projects he looks at. MD KK stated he did not receive training on quality improvement or performance improvement projects. When asked what changes the hospital made to Targeted Temperature Management, MD KK stated recent research led the hospital to increase the targeted temperature by two degrees. When asked if there was anything from the project data that led to changes in Targeted Temperature Management, MD KK stated no.</p> <p>During a concurrent interview and record review on 9/30/22 at 2:03 p.m. with MD KK and the second Co-Chair of the Critical Care Committee (MD MM), the Critical Care Committee Annual Report 2020, dated November 4th, 2020, was reviewed. The Critical Care Committee Annual Report Summary of Ongoing Activities 2020 included Code Blue Team Response Time Monitor 2020, Code Blue Outcomes 2020, and Post Cardiac Arrest Targeted Temperature Management (TTM) Monitor 2020. MD KK confirmed the Code Blue data project is a project they look at for quality improvement or performance improvement. MD MM confirmed the Targeted Temperature Management project is a project they use to monitor patient outcomes. MD KK stated he does not have data on the number of patients who met inclusion criteria for TTM compared with the number of patients who actually received it. When asked if there was any discussion about conducting quality improvement</p> | A 315 | (Please see Attachment A, pg. 21-22) | | |

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| A 315 | <p>Continued From page 70</p> <p>projects in the Critical Care Committee, MD MM stated it was mostly observational projects or projects from the Infection Prevention team. MD MM stated the Critical Care Committee would need more hospital support in terms of staffing to sort through patient data.</p> <p>During an interview on 9/29/22 at 10:58 a.m. with the President of the Enterprise Medical Leadership Council (MD HH), MD HH stated the Critical Care Committee is a subcommittee of the Medical Leadership Council. MD HH stated the Medical Leadership Council has oversight of quality improvement or performance improvement projects in terms of determining the project, data collection, data analysis, and changes made after data analysis.</p> <p>During an interview on 9/29/22 at 4:23 p.m. with the Quality Improvement Manager (QM NN), QM NN stated she views projects related to patient outcomes as quality improvement projects. QM NN stated the hospital is finally looking at service lines and clinical departments to improve clinical outcome measures. QM NN stated the hospital is not fully there yet. When asked if she would expect to see data collection, data analysis, and decision-making about interventions for outcomes data projects, QM NN stated the hospital is not there yet with their service lines and clinical departments. QM NN stated the service lines and clinical departments should be looking at their data and analyzing it. When asked what training service lines and clinical departments receive for process improvement, QM NN stated the goal is for the Quality Department to work collaboratively with all service lines and clinical departments. QM NN</p> | A 315 | (Please see Attachment A, pg. 21-22) | | |

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| A 315 | Continued From page 71 stated the hospital just started to work with the surgery department, but has not implemented anything yet. QM NN stated she is not aware of all Critical Care Committee projects and the reasons for the projects, and that is part of the struggle. During a review of the hospital's policy and procedure titled Performance Improvement Plan, dated June 6, 2000, indicated the hospital's Executive Team is responsible to the Governing Body for "... Provision of adequate resources for performance improvement activities ..." and "... Provision of adequate time for personnel to be trained and to participate in performance improvement activities ...". The policy noted "... The Medical Staff organization, within each division, as well as the [Hospital's] patient care service departments, share the responsibility for planning, designing, measuring, evaluating and improving the major functions of care service ...". | A 315 | (Please see Attachment A, pg. 21-22) | | |
| A 340 | MEDICAL STAFF PERIODIC APPRAISALS CFR(s): 482.22(a)(1) The medical staff must periodically conduct appraisals of its members. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to monitor clinical privileges [a list of specific services and procedures a healthcare provider is deemed qualified to provide or perform] for three of nine sampled providers (MD SS, MD TT, and MD UU) when: 1. Two physicians (MD TT and MD UU) were granted surgical privileges on reappointment without completing the required number of | A 340 | (Please see Attachment A, pg. 23-25) | | |

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| A 340 | <p>Continued From page 72 procedures.</p> <p>2. One telemedicine physician (MD SS) did not have documentation of clinical activity amount as required by Medical Staff Bylaws.</p> <p>These deficient practices had the potential for providers to be performing procedures without demonstrating continued competency and for placing patients at risk.</p> <p>Findings:</p> <p>1. During a review of the hospital's Enterprise Medical Staff Bylaws, approved 12.15.20, indicated, "... Basis for Privilege Determinations ... Privileges shall be granted only to those Practitioners ... who satisfy the established criteria, as evidenced by the applicant's ... performance of a sufficient number of procedures each year to maintain current clinical competence ...".</p> <p>During a concurrent interview and record review on 9/29/22 at 10:58 a.m. with the Medical Staff Quality Improvement Coordinator (MSQIC), Hospital Medical Director (MD GG), Program Manager of Medical Staff Office (MSOM), and President of the Enterprise Medical Leadership Council (MD HH), the credentialing files of MD TT and MD UU were reviewed. MD TT was reappointed to the medical staff in April 2022. MD TT's granted privileges included Insertion and Maintenance of Pulmonary Artery Catheter [insertion of long thin tube into the right side of</p> | A 340 | (Please see Attachment A, pg. 23-25) | |
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| A 340 | <p>Continued From page 73</p> <p>the heart and the blood vessels leading to the lungs], and Sentinel Lymph Node Biopsy [procedure to see if cancer has spread beyond the initial tumor]. MD UU was reappointed to the medical staff in September 2022. MD UU's granted privileges included Insertion and Maintenance of Pulmonary Artery Catheter, and Sentinel Lymph Node Biopsy. A review of a blank template for Privileges in General Surgery, undated, noted criteria for renewal of specific privileges. For Insertion and Maintenance of Pulmonary Artery Catheter, "... documentation of successful placement and management of at least 1 pulmonary artery catheter ..." was required. For Sentinel Lymph Node Biopsy, "... Completion of a minimum of 10 sentinel lymph node biopsy cases in the credentialing cycle (2 years) ..." was required. When asked if the hospital was tracking MD TT and MD UU's case numbers for pulmonary artery catheter insertions and sentinel lymph node biopsies, MD GG stated they would check.</p> <p>During a concurrent interview and record review on 9/30/22 at 1:30 p.m. with the MSQIC, MD GG, and MD HH, the credentialing files of MD TT and MD UU were reviewed. MD HH confirmed that MD TT did not have any pulmonary artery catheter insertions or sentinel lymph node biopsies documented in the previous reappointment cycle. The MSQIC confirmed that MD UU did not have ten sentinel lymph node biopsies and did not have any pulmonary artery catheter insertions documented in the previous reappointment cycle. MD GG and MD HH confirmed that MD TT and MD UU were granted pulmonary artery catheter insertion and sentinel lymph node biopsy privileges without meeting</p> | A 340 | (Please see Attachment A, pg. 23-25) | |

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

PRINTED: 10/26/2022
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| A 340 | <p>Continued From page 74</p> <p>case number criteria. MD HH stated the credentialing staff did not flag these discrepancies.</p> <p>2. During a concurrent interview and record review on 9/28/22 at 10:35 a.m. with the Medical Staff Quality Improvement Coordinator (MSQIC), Hospital Medical Director (MD GG), Program Manager of Medical Staff Office (MSOM), President of the Enterprise Medical Leadership Council (MD HH), and Immediate Past President of the Enterprise Medical Staff (MD JJ), the credentialing file of MD SS was reviewed. MD SS was reappointed to the medical staff in January 2021 as a telemedicine physician. The hospital's focused evaluation for MD SS for July- Dec 2021, undated, did not include patient volume numbers. The ongoing evaluation for MD SS from the telemedicine company for July to Dec 2021, signed 2/16/2022, did not include patient volume numbers. MD JJ stated, since the hospital does not have any clinical activity numbers or patient volume documented for MD SS, the hospital has accepted the ongoing evaluation from the telemedicine company. MD JJ confirmed, however, that there were also no clinical activity numbers from the telemedicine company.</p> <p>During an interview on 9/29/22 at 10:58 a.m. with the MSOM, MD HH, MD GG, and MSQIC, MD GG stated MD SS had low patient volume numbers at the hospital. When asked how the hospital knows if MD SS had low volume numbers everywhere, MD GG stated they did not have patient volume numbers from the telemedicine company.</p> | A 340 | (Please see Attachment A, pg. 23-25) | | |

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| A 340 | Continued From page 75 During a review of the hospital's Medical Staff Rules, approved May 2017, indicated, "... The Medical Staff shall, in timely fashion, seek to verify the additional information made available on each reappointment application and to collect any other materials or information deemed pertinent ... The information shall address ... Level/amount of clinical activity (patient care contacts) at the hospital ...". | A 340 | (Please see Attachment A, pg. 23-25) | |
| A 341 | <p>MEDICAL STAFF CREDENTIALING CFR(s): 482.22(a)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to abide by its credentialing process for two of nine sampled providers (MD SS and MD RR) when:</p> <ol style="list-style-type: none"> 1. There was no documentation that one physician (MD SS) completed required initial proctoring. 2. One physician (MD RR) had privileges [a list of specific services and procedures a healthcare provider is deemed qualified to provide or perform] to admit patients and perform surgical | A 341 | (Please see Attachment A, pg. 26-28) | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 341 | <p>Continued From page 76 procedures despite being a telemedicine physician.</p> <p>These deficient practices had the potential for providers to be performing procedures without demonstrating competency and for placing patients at risk.</p> <p>Findings:</p> <p>1. During a review of the hospital's Enterprise Medical Staff Bylaws, approved 12.15.20, indicated all initial appointees to the Medical Staff are subject to a focused evaluation. The Medical Staff Bylaws noted the focused evaluation generally includes a period of proctoring [evaluation of a healthcare provider's skills and knowledge to determine his or her ability to exercise certain privileges]. The Medical Staff Bylaws noted, "... Whenever proctoring is imposed, the number (or duration) and types of procedures to be proctored shall be delineated ..."</p> <p>During a concurrent interview and record review on 9/28/22 at 10:35 a.m. with the Medical Staff Quality Improvement Coordinator (MSQIC), Hospital Medical Director (MD GG), Program Manager of Medical Staff Office (MSOM), President of the Enterprise Medical Leadership Council (MD HH), and Immediate Past President of the Enterprise Medical Staff (MD JJ), the credentialing file of MD SS was reviewed. MD SS was initially appointed to the medical staff in January 2017 as a telemedicine physician. A</p> | A 341 | (Please see Attachment A, pg. 26-28) | |

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

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| A 341 | <p>Continued From page 77</p> <p>review of MD SS's privileges form, signed 12/12/16, indicated five patient chart reviews were required for proctoring of initial privileges. The MSQIC stated they were unable to find MD SS's initial proctoring. MD HH and MD JJ confirmed MD SS was supposed to complete initial proctoring when he joined the hospital's medical staff.</p> <p>2. During a review of the hospital's Medical Staff Rules, approved May 2017, indicated, "... The Telemedicine Staff shall consist of the members who provide diagnostic and therapeutic care remotely ...". Under Summary of Applicable Prerogatives [a right or privilege exclusive to a particular individual or class], Responsibilities, Etc, for Telemedicine Staff, there was no privilege to admit patients. The Medical Staff Rules noted telemedicine staff are eligible for telemedicine privileges only. The Medical Staff Rules defined telemedicine as "... The total or shared delivery of healthcare services ... utilizing information and communication technologies to enable the diagnosis, consultation, treatment ... of patients at a distance ...".</p> <p>During a review of the hospital's Enterprise Medical Staff Bylaws, approved 12.15.20, indicated, "... Admitting Privileges ... Only Medical Staff members with admitting privileges may independently admit patients to the hospital ...".</p> <p>During a concurrent interview and record review on 9/28/22 at 10:35 a.m. with the Medical Staff Quality Improvement Coordinator (MSQIC), Hospital Medical Director (MD GG), Program</p> | A 341 | (Please see Attachment A, pg. 26-28) | |

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

PRINTED: 10/26/2022
FORM APPROVED
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| A 341 | <p>Continued From page 78</p> <p>Manager of Medical Staff Office (MSOM), President of the Enterprise Medical Leadership Council (MD HH), and Immediate Past President of the Enterprise Medical Staff (MD JJ), the credentialing file of MD RR was reviewed. MD RR was reappointed to the medical staff in April 2022 as a telemedicine physician. A review of MD RR's requested and granted clinical privileges from April 2022 included, "... Admit ... and perform surgical and non-surgical procedures on patients of all ages ..." and to use laser. When asked why a telemedicine physician had privileges to admit patients and perform surgical procedures, MD GG and MD HH stated they were revising the hospital's privileging process. MD JJ stated they recognized it was a gap they had and they were working to correct it. A review of the hospital's focused evaluation for MD RR for July-December 2021, undated, did not include any patient volume numbers. The MSQIC stated they were not tracking MD RR's patient volume numbers at the hospital. MD JJ stated they should be tracking it.</p> <p>During an interview on 9/29/22 at 10:58 a.m. with the MSOM, MSQIC, MD GG, and MD HH, MD HH stated MD RR transitioned from a different staff category to telemedicine staff in April 2022. MD HH stated MD RR was not supposed to keep admit and surgical privileges when he transitioned to telemedicine staff. MD HH stated the hospital's privilege set needs to be updated. When asked if there was supposed to be a review to see if clinical privileges are still appropriate when providers switch staff categories, MD HH stated there should be a more detailed discussion about the provider at credentialing meetings.</p> | A 341 | (Please see Attachment A, pg. 26-28) | |

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

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FORM APPROVED
OMB NO. 0938-0391

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| A 341 | Continued From page 79 | A 341 | (Please see Attachment A, pg. 26-28) | | |
| A 353 | <p>MEDICAL STAFF BYLAWS CFR(s): 482.22(c)</p> <p>The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure the Patient Safety Committee met monthly as required by the Medical Staff Bylaws. This deficient practice had the potential for patient safety events to not be discussed timely.</p> <p>Findings:</p> <p>During a review of the hospital's Medical Staff Rules, revised May 2017, indicated the Patient Safety Committee was a committee of the Medical Staff. The Medical Staff Rules indicated the Patient Safety Committee shall "... Develop, implement and annually evaluate a written Patient Safety Program ...". The Medical Staff Rules indicated the Patient Safety Committee "... shall meet monthly ...".</p> <p>During a review of the hospital's policy and procedure titled Patient Safety Plan, undated,</p> | A 353 | (Please see Attachment A, pg. 28-29) | | |

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

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| A 353 | <p>Continued From page 80</p> <p>indicated the Patient Safety Committee is responsible for "... Reviewing reports regarding patient safety events, including potential or no-harm errors to hazardous conditions and sentinel events ... Monitoring the implementation of corrective actions for patient safety events ... Making recommendations to eliminate or mitigate future patient safety events ... Assuring a reliable process for analyses, including, but not limited to, root cause analyses of patient safety events ...".</p> <p>The policy defined Sentinel Event as "... An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof ...". The policy defined Patient Safety Events as including "... all adverse events or potential adverse events that are determined to be preventable ... these events include those deemed reportable by the California Center for Medicare and Medicaid Services (CMS), the California Health and Safety Code, and The Joint Commission (TJC) ...".</p> <p>During a review of the hospital's Patient Safety Committee meeting minutes for twelve months, indicated the Patient Safety Committee met in August 2021, October 2021, December 2021, February 2022, March 2022, April 2022, May 2022, and August 2022.</p> <p>During an interview on 9/22/22 at 1:40 p.m. with the Hospital Medical Director (MD GG), MD GG stated both in-progress and completed root cause analyses [method used to analyze adverse patient events, which focuses on identifying underlying problems that increase likelihood of errors] are discussed at Patient Safety Committee. MD GG stated the Quality Department conducts the root cause analyses.</p> | A 353 | (Please see Attachment A, pg. 28-29) | |

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| A 353 | Continued From page 81 During an interview on 9/30/22 at 1:30 p.m. with the Hospital Medical Director (MD GG), MD GG stated he was the chair of the Patient Safety Committee. MD GG confirmed the Medical Staff Bylaws note the Patient Safety Committee is supposed to meet monthly. MD GG stated the Patient Safety Committee does not meet if he is on vacation, if there are not enough committee members, or if the committee does not have enough to speak about. During an interview on 9/22/22 at 9:54 a.m. with the Hospital Medical Director (MD GG), MD GG stated Patient Safety Committee information is communicated up to the hospital's Medical Leadership Council, then to the Enterprise Medical Executive Committee, and then to the Governing Body. | A 353 | (Please see Attachment A, pg. 28-29) | | |
| A 385 | NURSING SERVICES CFR(s): 482.23 The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to comply with the Condition of Participation for Nursing Services as evidenced by: 1. Failure to implement a physician order (refer to A-0398); 2. Failure to assess and manage patients' pain (refer to A-0398); | A 385 | Please see Attachment A, pg. 29 and please refer to tag: A398 pg. 29-41 A405 pg. 41-43 A407 pg. 43-44 | | |

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| A 385 | Continued From page 82 3. Failure to complete nursing documentation by nursing staff (refer to A-0398); 4. Failure to validate staff competency prior to providing care (refer to A-0398); 5. Failure to keep potentially sharp items in a designated container (refer to A-0398); 6. Failure to include an indication for a drug (refer to A-0405); 7. Failure to authenticate a verbal order (refer to A-0407). The cumulative effect of these systemic problems resulted in the hospital's inability to ensure the provision of quality health care in a safe environment. | A 385 | Please see Attachment A, pg. 29 and please refer to tag: A398 pg. 29-41 A405 pg. 41-43 A407 pg. 43-44 | | |
| A 398 | SUPERVISION OF CONTRACT STAFF CFR(s): 482.23(b)(6) 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). This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to ensure nursing staff followed the hospital's policies for 11 patients when: | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

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FORM APPROVED
OMB NO. 0938-0391

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| A 398 | Continued From page 83 1. For Patient 1, environmental safety concerns were not identified and corrected per policy. This failure resulted in Patient 1, a suicidal patient having the means and opportunity to throw a hospital room chair through the window and jump out leading to Patient 1's death 2. For Patient 16, staff did not ensure a safe environment, initiate the chain of command, and provide constant observation. This failure resulted in Patient 16 eloping from the emergency department (ED) and jumping from a parking structure, which caused injuries including multiple facial fractures (broken bone), pelvis fracture, wrist fracture, foot fracture, pulmonary contusions (bruises), pneumothorax (collapsed lung), retroperitoneal hematoma (bleeding in part of the abdominal cavity). During Patient 16's three-month hospitalization, he was admitted to the Intensive Care Unit (ICU), was placed on a ventilator (machine that helps a person breathe), and required a feeding tube for nutrition. Patient 16 was also diagnosed with closed head injury (injury to the brain with no break in the skull), severe traumatic brain injury (damage to the brain caused by an external force), hypoxic-ischemic infarcts (death of tissue due to inadequate oxygen in the blood and inadequate blood supply), altered mental state (symptoms that can range from confusion to loss of consciousness), lactic acidosis (buildup of lactic acid in the bloodstream), oropharyngeal dysphagia (swallowing problems in the mouth and/or throat), voice and resonance disorder (disorder that affects the quality of the voice during speech), cognitive communication deficit (difficulty communicating), and difficulty walking. | A 398 | (Please see Attachment A, pg. 29-41) | | |

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| A 398 | <p>Continued From page 84</p> <p>Patient 16 required multiple surgeries and extensive rehabilitation treatments over several months.</p> <p>3. For Patient 10, the order for neuro checks (neurological examinations, assessment of cognitive and motor responses to determine whether the nervous system is impaired) was not implemented.</p> <p>4. For Patients 13, 21 and 25, pain assessment and management were not provided.</p> <p>5. For Patients 7, 8, 11, hourly observations were not consistently completed and for Patients 10 and 15, observations and safety interventions documentation were not consistently completed by the sitter and licensed nurses.</p> <p>6. For Patient 45, nursing staff failed to document assessment/reassessment in the ED.</p> <p>7. Staff competency was not specific to the tasks or criteria for sitter.</p> <p>8. For Patient 21, a laboratory kit with butterfly needles and syringe inside the plastic kit was exposed on top of the red sharp container inside her room.</p> <p>These failure affected and had the potential to affect the health and safety of patients.</p> <p>Findings :</p> <p>1. Record review on 9/20/22 at 11:00 a.m. indicated Patient 1 was admitted to the hospital</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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| A 398 | <p>Continued From page 85</p> <p>on 8/12/22 for self-inflicted stab wounds to the abdomen and wrist from a suicide attempt. Patient 1 had been placed on a 5150 hold by law enforcement. A 5150 is a 72 hour hold when a patient is considered a danger to self or others.</p> <p>Patient 1 was brought to the operating room for repair of the lacerations to his abdomen and wrist. Patient 1 was then brought to the forth floor medical surgical unit for his recovery.</p> <p>Record review on 9/20/22 at 11:30 a.m. of a Patient Care Overview, dated 8/12/22 at 10:25 p.m. indicated Patient 1 was on 5150 hold and had a 1:1 sitter at the bedside. "Patient denied suicidal ideation, stated the voices come and go, but no current thought or plan of harming himself."</p> <p>Record review of a nurses note dated 8/13/22 at 5:11 am indicated, "Patient denies SI/HI [suicidal/homicidal ideations] but states he is still hearing voices that are telling him he should have gone to the hotel. 1:1 sitter at bedside for 5150 DTS [danger to self]."</p> <p>Record review at 11:45 a.m. of the Initial Psych Consult Note dated 8/13/22 at 2:13 p.m. indicated Patient 1 "presenting with self-inflicted slab wounds in response to incessant command auditory hallucinations telling him to kill himself."</p> <p>Patient 1's stated chief complaint was "The voices were telling me you have only 8 more days to kill yourself. The next day they would say that I have only 7 more days."</p> <p>Further record review of the Course, Assessment</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

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| A 398 | <p>Continued From page 86 and Plan indicated, "Patient has a history of treatment resistant Schizoaffective Disorder. We will extend his 5150 hold onto 5250 [5250 extends the hold to 14 days]."</p> <p>Further record review indicated Patient 1 continued to have a 1:1 sitter at all times and record review on 9/20/22 at 12:00 p.m of the Death Summary indicated, "On the evening of 8/17/22 at approximately 20:56 (8:56 p.m.) Code Gray was called as the patient was found to be agitated and physically assaulting the sitter in his room."</p> <p>"The RN had to physically pull the sitter from the room for her safety as she was actively being hit by the patient. The patient tried to lunge at staff and the door was closed for the staff safety. The door remained closed for approximately 5 seconds and when it was reopened, the patient was seen back near his bed and appeared to be searching for something while continuing to yell. He then grabbed a chair, lifted it, and broke the window open with the chair. He then proceeded to jump out the window of his room on the 4th story of building E. MD was notified the patient had been pronounced dead on the scene at 21:12 (9:12 p.m.) by EMS [emergency medical services]."</p> <p>Record review the same day at 12:30 p.m. of the Inpatient Psychiatry Consult Note dated 8/17/22 at 9:12 p.m. indicated, "Patient 1 was seen between 2 - 3 p.m. Patient 1 was seated in his chair. Patient complained about his abdomen being distended. He appeared calm but anxious. He acknowledges auditory hallucinations."</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 398 | <p>Continued From page 87</p> <p>"I reassured him that we were working on getting him admitted to a psychiatric facility so that he can receive appropriate help."</p> <p>During an interview on 9/21/22 at 10:45 a.m., Sitter C stated she was the sitter for Patient 1 on the evening of 8/17/22. Sitter C stated Patient 1 had gone into the bathroom and when he came out, he stated he was bleeding. Sitter C stated she asked to see and Patient 1 attacked her. Sitter C stated staff rushed to pull her out of the room as Patient 1 took the chair and hit the window and jumped.</p> <p>During an observation and interview on 9/23/22 at 2:30 p.m., assistant nurse manager (ANM) on the 4th floor medical-surgical unit stated she had been the charge nurse on the evening of 8/17/22. She stated she had been at the nurses station and heard yelling and realized it was Patient 1. Staff responded and had trouble opening the door of Patient 1's room. She stated she could see Patient 1 blocking the door and hitting Sitter C.</p> <p>ANM stated she yelled for help and called Code Grey for security. She stated staff assisted Sitter C to exit the room and she could see Patient 1 pacing in the room. ANM stated Patient 1 picked up the hospital chair, broke the window, and jumped to his death.</p> <p>ANM stated in less than a minute EMS responded to the construction area where Patient 1 had fallen and Patient 1 was unable to be revived.</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

PRINTED: 10/26/2022
FORM APPROVED
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| A 398 | <p>Continued From page 88</p> <p>ANM stated the hospital room was presently set up the same way as it had been when Patient 1 was present. The room contained a bed, a computer on wheels, IV pump, cords for the nurses call light and computer, and a padded chair.</p> <p>ANM stated the rooms were furnished the same way for all patients and the chair was a typical hospital room chair and could be moved around the room.</p> <p>During an observation at the same time, the chair could be lifted and was not anchored to the floor.</p> <p>Record review on 9/23/22 at 3:00 p.m. of the At-Risk Safety checklist (every shift) indicated from 8/12/22 until 8/17/22 the points for assessment of the room safety were determined as 'met'.</p> <p>During an interview on 9/26/22 at 9:45 a.m., MD F indicated Patient 1 was very ill, but calm, more so depressed. MD F stated Patient 1 wouldn't have hurt himself except he could not resist the voices telling him to do so.</p> <p>Record review on 9/26/22 at 11:00 a.m. of the Hospital Policy "Suicide/Safety Precautions and Care of Patient in Non- Behavioral Health Areas dated 6/24/2020 indicated: " A. Suicidal, potentially suicidal, and patients with self-harming behaviors will be treated in a safe environment to protect the patient from self harm. B. Special safeguards will be provided to protect the patient from self harm when the patient is assessed to be suicidal, potentially suicidal, and/or endanger of self harm."</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | Continued From page 89 Further record review of the policy contained the "Environment of Care Checklist for Safety of Suicidal Patients and Patients with Self-Harming behavior. This checklist is a tool and should be used to identify and correct any environmental safety concerns to prevent inpatient suicide attempts. Documentation of the points below will be performed in the electronic medical record." The points indicated in the policy included: "4. Is the area free of lamps, any any items that could be used as a weapon? ... 6. Is furniture secured or heavy enough to prevent it from being picked up and thrown or moved to block door?" 2. Review of Patient 16's ED Provider Notes from a previous hospital, dated 5/12/21 at 9:56 p.m., indicated the following: Patient 16 was a 19-year-old male with diagnoses including Coronavirus 2019 (COVID-19, a new strain of virus that can cause mild to severe illness) and adjustment disorder (emotional or behavioral symptoms in response to being unable to cope with a source of stress). Patient 16 was brought to a previous hospital's ED "by ambulance after he was found running around the street naked. Per EMS [Emergency Medical Services] PD [police department] apprehended him, remove handcuffs, patient took off running, and thus was taken down." Patient 16 was placed on a 5150 hold (when a designated professional evaluates a person to be a danger to self or to others due to a mental health disorder, the person can be detained for a 72-hour psychiatric hospitalization) for gravely disabled and danger to self. On 5/13/21 at 11:28 a.m., prior to being | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
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| A 398 | <p>Continued From page 90</p> <p>transferred from a previous hospital to this hospital, "Patient 16 ran out of [a previous hospital's] emergency department, security guard cannot catch up and he got away. Police and EMS found him down the street ... he is otherwise going to be going to EPS [Emergency Psychiatric Services] at this time."</p> <p>Review of Patient 16's Application for Assessment, Evaluation, and Crisis Intervention or Placement for Evaluation and Treatment (also known as 5150 or psychiatric hold), dated 5/12/21 at 11 p.m., indicated Patient 16 was a danger to himself and was a gravely disabled adult because Patient 16's "father and mother concerned as he asked his father to choke and kill him, wanted to take the Samurai sword to stab himself, and said he wished they had a gun so he could blow his head off."</p> <p>Review of the previous hospital's Patient Care Timeline, dated 5/12/21 to 5/13/21 indicated Patient 16 was discharged from the previous hospital on 5/13/21 at 12:03 p.m.</p> <p>Review of Patient 16's EPS Notes, dated 5/13/21 at 1:30 p.m., indicated Patient 16 was seen for an initial RN assessment.</p> <p>Review of Patient 16's EPS Provider Notes, dated 5/13/21 at 3:38 p.m. indicated Patient 16 had a temperature of 101.5, was coughing, and complaint of malaise. The notes indicated the plan was to send Patient 16 to the ED for medical clearance, continue with 5150, and the Patient 16 can be sent back to EPS after medical clearance.</p> <p>Review of Patient 16's EPS Notes, dated 5/13/21</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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| A 398 | <p>Continued From page 91</p> <p>at 5:25 p.m. indicated EPS Registered Nurse (EPS RN) escorted Patient 16 to the ED with one EPS mental health worker, a protective services officer, and ED tech due to AWOL (absent without official leave) risk. The notes indicated EPS RN, "Gave SBAR [Situation, Background, Assessment, Recommendation, a communication tool] report to Assigned male nurse [Registered Nurse T (RN T)] and notified him of [Patient 16's] high potential AWOL risk due to him awoling from prior ED prior to EPS."</p> <p>Review of the County Protective Services Incident Report, dated 5/13/21 indicated Protective Services Officer (PSO) documented, "On Thursday 5/13/21 at approximately 1720 [5:20 p.m.] Hours ... I was dispatched to take [Patient 16] from Emergency Psychiatric services (EPS) overflow unit to the Emergency room (ER) Due to COVID like symptoms. Upon arrival staff informed me that the patient was a flight risk, he was then secured to the chair for transport to the Emergency room. Patient [16] went to Emergency Room 19, upon arrival I informed the ER staff [RN T] that [Patient 16] was a flight risk and could possibly try to elope. Staff put the patient in the room and then assigned a sitter for the patient no restraints or medication was given at the time.</p> <p>Review of Patient 16's Patient Care Timeline from Patient 16's first visit to this hospital's ED, dated 5/13/21, indicated the following: On 5/13/21 at 5:43 p.m., Patient 16 arrived in this hospital's ED. On 5/13/21 at 5:59 p.m., Patient 16's EPS Legal Status was "5150" and the reason for 5150 was "Danger to Self; Gravely Disabled."</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | <p>Continued From page 92</p> <p>On 5/13/21 at 6 p.m., RN T documented, "[Patient 16] remains 5150, sitter present at bedside."</p> <p>On 5/13/21 at 6:10 p.m. RN T documented, "[Medical Doctor VV (MD VV) reports contacted EPS MD and reports ok to transfer pt [Patient 16] back to EPS."</p> <p>On 5/13/21 at 6:30 p.m., RN T documented, "Sitter present; awaiting transfer to EPS."</p> <p>On 5/13/21 at 6:33 p.m., RN T documented, "[EPS] RN reports bed not available until 1900 [7 p.m.]."</p> <p>On 5/13/21 at 6:55 p.m., RN T documented, "[At] approximately 1847 [6:47 p.m.] Pt [Patient 16] removed IV [intravenous catheter placed in the vein to administer fluids or medication] and exited assigned room and exited ER [emergency room]. Pt not receptive to verbal redirection to return to assigned room. Pt continues to refuse verbal redirection and ran out of ER. 3 ER Staff followed pt past ED CT [computed tomography]. Continued to provide verbal redirection and encouragement to return to ER, pt continues to run and observed pt running toward M building where pt [patient] is longer visible."</p> <p>During observation of 5/13/21 ED video surveillance on 9/26/22 at 11:58 a.m. and concurrent interview with the Emergency Department Nurse Manager S (NM S), the Director of Nursing Critical Care (DNCC), RN T, and Registered Nurse U (RN U), the following was observed:</p> <p>On 5/13/21 at 6:39:59 p.m., Patient 16 walked out of his room wearing light blue-green scrubs, while Sitter X sat at a workstation on wheels (WOW) with his back toward the door of Patient 16's room.</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | <p>Continued From page 93</p> <p>On 5/13/21 at 6:40:04 p.m., Patient 16 walked past Sitter X.</p> <p>On 5/13/21 at 6:40:07 p.m., Patient 16 walked past RN U, who was talking to a staff member by the nurse's station, and Patient 16 continued walking down the hallway.</p> <p>On 5/13/21 at 6:40:09 p.m., Patient 16 walked out of video view. Sitter X remained seated at the WOW and RN U continued speaking to another staff member.</p> <p>On 5/13/21 at 6:40:22 p.m., RN U grabbed supplies and walked down the hallway towards Patient 16's room.</p> <p>On 5/13/21 at 6:40:45 p.m., a janitorial staff member and RN U looked towards Patient 16's room. RN U pointed in the direction of Patient 16's room.</p> <p>On 5/13/21 at 6:40:53 p.m., Sitter X looked inside Patient 16's room.</p> <p>On 5/13/21 at 6:41:03 p.m., Sitter X got up from the chair and walked down the hallway.</p> <p>On 5/13/21 at 6:41:17 p.m., RN U looked inside patient room. RN T came into video view.</p> <p>On 5/13/21 at 6:41:24 p.m., RN T came out of video view.</p> <p>On 5/13/21 at 6:42:15 p.m., after leaving another ED room, RN U stood by the nurse's station.</p> <p>On 5/13/21 at 6:42:55 p.m. Patient 16 walked down the hallway toward his room with Sitter X behind him.</p> <p>On 5/13/21 at 6:43:06 p.m., Sitter X brought Patient 16 back to his room.</p> <p>On 5/13/21 at 6:43:18 p.m., Sitter X closed the door to Patient 16's room.</p> <p>On 5/13/21 at 6:43:40 p.m., Sitter X walked away from Patient 16's room.</p> <p>On 5/13/21 at 6:43:43 p.m., Sitter X walked past RN U, who remained at the nurse's station.</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | <p>Continued From page 94</p> <p>On 5/13/21 at 6:43:45 p.m., Sitter X walked out of video view.</p> <p>On 5/13/21 at 6:44:18 p.m., Sitter X walked back toward Patient 16's room.</p> <p>On 5/13/21 at 6:44:25 p.m., Sitter X placed an item on the WOW in front of Patient 16's room and walked away from Patient 16's room. Sitter X walked past RN U.</p> <p>On 5/13/21 at 6:44:29 p.m., Sitter X walked out of video view.</p> <p>On 5/13/21 at 6:44:44 p.m., RN U walked out of another ED room.</p> <p>On 5/13/21 at 6:44:48 p.m., Patient 16 opened the door to his room.</p> <p>On 5/13/21 at 6:44:52 p.m. Patient 16 stepped out of the room and turned toward RN U.</p> <p>On 5/13/21 at 6:44:57 p.m., RN U pointed toward Patient 16's room and Patient 16 turned his back to RN U.</p> <p>On 5/13/21 at 6:45:02 p.m., Patient 16 walked through exit doors. RN U followed behind Patient 16.</p> <p>On 5/13/21 at 6:45:05 p.m., RN T and another staff member followed Patient 16 through the exit doors.</p> <p>From 5/13/21 at 6:44:29 p.m. to 5/13/21 at 6:45:17 p.m., Sitter X was not in video view.</p> <p>RN T stated he was Patient 16's assigned nurse. RN T stated he was not aware Patient 16 eloped at a prior hospital prior to coming to this hospital's ED. He stated when patients are on 5150 or come from EPS, patients are given scrubs to wear in a specific "teal" color, so staff can identify them. RN U stated Patient 16 was already wearing the distinct color scrubs when he came from EPS. RN U stated it was noticeable to see a patient in those colored scrubs, but he did not</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | <p>Continued From page 95</p> <p>notice Patient 16 walk to the bathroom. RN T stated he did not notice Patient 16 walk to the bathroom. RN T stated he was at the nurse's station and did not see Patient 16 nor Sitter X walk by. RN U stated when he noticed Patient 16 was gone, he told Sitter X to locate the patient. RN U stated he remembered having a conversation with Sitter X saying he should be with the patient all the time. RN U stated he kept that information between him and Sitter X. RN T stated he was not informed Patient 16 left his room and went to the bathroom unsupervised. RN U stated if he felt the sitter could do his job, he would not escalate the sitter's lapse to the charge nurse. RN U stated after Patient 16 was returned to his room, he did not see Sitter X walk away from the Patient 16's room. RN U stated when caring for 5150 patients, he relies on the sitter and stated Sitter X did not say anything to him. NM S stated she did not expect the sitter's lapse to be escalated to the charge nurse because Patient 16 was found.</p> <p>During an interview on 9/22/22 at 3:36 p.m., with NM S and the DNCC, NM S stated they do their best to find a room close to the nurse's station for 5150 patients. NM S stated the ED has a high volume of patients, so they put 5150 patients in any room available. The DNCC stated they assign a sitter for 5150 patients and the 5150 patients are given scrubs to identify that identify that they are 5150 patients. The DNCC stated a safety sweep of the room should be done to remove anything unnecessary. She stated the sitter providing constant observation should be within arms reach of the patient. The DNCC stated in this case, Patient 16 had COVID-19, so the sitter's expectation was to be outside the door</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

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| A 398 | <p>Continued From page 96</p> <p>with the door closed and to visualize the patient through the window on the door. She stated Sitter X should have had the appropriate PPE, an N95. The DNCC stated Sitter X had his back towards the door and was not paying attention to Patient 16. She stated Sitter X returned Patient 16 to the room. NM S stated Sitter X left the patient to look for an N95.</p> <p>During an interview on 9/22/22 at 11 a.m., RN T stated he did not remember how he was assigned or informed about Patient 16. RN T stated for 5150 patients, they always have a sitter. He stated part of a nurse's assessment is to do a primary sweep or safety check of the room. RN T stated the nurse or sitter should do a safety check. RN T stated he remembered when he left the Patient 16, Sitter X was with Patient 16. But when Patient 16 eloped from the ED, Sitter X was not there.</p> <p>During an interview on 9/23/22 at 11:15 a.m, Quality Improvement Coordinator V (QC V) confirmed there was no documentation that indicated a safety check of Patient 16's room was done.</p> <p>Review of Patient 16's ED Provider Notes from Patient 16's second visit to this hospital's ED, dated 5/13/21 at 9:59 p.m., indicated Patient 16 was "covid pos [positive] on 5150 eloped from ED" and "jumped off 3 floor parking garage and landed in tree." The notes indicated, "19 yo M [year old male] presenting after 30' [foot] fall of building, landed face first. On arrival, bagged with O2 sats [oxygen saturation, level of oxygen in blood, normal levels around 90-100%] in 70s. Intubated [inserted tube through the mouth or</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 398 | <p>Continued From page 97</p> <p>nose into the airway to help with breathing] in trauma bay with bilateral breath sounds, persistent sats in 80s. GCS [Glasgow Coma Scale, scoring system to determine level of consciousness and gauge severity of brain injury based on eye response, verbal response, and motor response, scores range from 3 to 15; GCS 3 to 8 classified as severe brain injury)] 4, pupils 3 to 2. Blood at face and large chin lac [laceration], agonal respirations [difficulty breathing, gasping] prior to intubation."</p> <p>Review of Patient 16's Trauma - History and Physical, dated 5/13/21 at 10:10 p.m., indicated, "Severe polytrauma [multiple injuries] following fall from fourth floor of a parking structure, COVID-19 positive, CHI (closed head injury) with decreased mental status, unknown period of hypoxia [low oxygen in the tissues] following his fall, complex facial fractures, bilateral orbital fractures (broken bones around eye), bilateral frontal sinuses (hollow space in the bones around the nose), mandible (jaw) and right-sided hard palate (roof of mouth) fractures, consistent with a LeFort III (type of fracture that affects the face), right-sided pneumothorax (a collapsed lung. It occurs when air leaks into the space between the lungs and chest wall), S/P (status post, after) placement of a chest tube, possible aspiration (material entering airway or lungs accidentally), retroperitoneal hematoma with a 2 cm (centimeter, unit of measurement) by 0.6 cm hyper-density next to the left adrenal gland (a small, triangular-shaped gland located on top of the kidney. It produces hormones), possibly consistent with an active extravasation (leakage) of blood; fracture of the left iliac wing (part of pelvis) and severe lactic acidosis (lactic acid</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 98</p> <p>build up in the bloodstream. Lactic acid is produced when oxygen levels become low in cells within the areas of the body where metabolism takes place).</p> <p>On the same report, dated 5/13/21, it also indicated the following plans: intubation; fluid resuscitation (replenish body fluid); blood transfusion; admission to Intensive Care Unit (ICU); ear, nose and throat specialist (ENT) consultation for severe facial fractures; interventional radiology (IR) to consult to assess retroperitoneal bleeding; ophthalmology to consult regarding orbital fractures; psychiatry to consult regarding suicidal ideation (SI); orthopedics to consult regarding iliac wing fracture; further radiographs of the right knee; continue tranexamic acid (TXA, medication given to prevent or reduce bleeding); and transfuse as necessary.</p> <p>Review of Patient 16's General Surgery/Trauma Discharge Summary, dated 6/12/21, indicated he had the following operations and procedures performed:</p> <ol style="list-style-type: none"> 1. Left distal radius (wrist) open reduction and internal fixation (ORIF, surgery to fix broken bones) on 5/25/21; 2. Right ORIF of first and third metatarsal (bones in foot) on 5/25/21; 3. Percutaneous endoscopic gastrostomy (PEG, a procedure to place tube into stomach to provide nutrition) on 5/27/21; 4. Tracheotomy (a procedure to place tube into the trachea [windpipe] to help a person to breathe), MMF (maxillomandibular fixation, wiring the jaws shut) on 5/27/21. | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 99</p> <p>On the same report, dated 6/12/21, it indicated Patient 16 was discharged to another hospital on 6/12/21 for "definitive management of le forte 3 fracture."</p> <p>Review of Patient 16's Physician Discharge Summary, dated 7/8/21, indicated Patient 16 underwent surgery for complex facial repair in another hospital on 6/16/21. Patient 16 was readmitted back to this hospital on 6/28/21 for continuation of treatment. Patient 16 was transferred to the acute rehabilitation unit (ARU) on 7/8/21.</p> <p>Review of Patient 16's Physical Medicine and Rehabilitation Discharge Summary, dated 8/27/21, indicated Patient 16 underwent surgery for removal of maxillary and mandibular hardware on 7/9/21. It also indicated that Patient 16 participated in comprehensive rehabilitation with daily psychiatric management, OT (occupational therapy), PT (physical therapy), SLP (speech therapy), recreational therapy, neuropsychology and 24-hour nursing to address self-care, bed mobility, transfers, wheelchair mobility, balance, pre-gait and gait activities, neuromuscular facilitation, swallowing, nutrition, communication, cognitive retraining and memory compensatory strategies, bowel and bladder management, safety, behavioral management, equipment evaluation, caregiver training and community reentry.</p> <p>Review of a letter addressed to Sitter X, "Subject: Final Disciplinary Action - Termination," dated 10/14/21, indicated Sitter X violated the hospital's administrative policies and procedures, including</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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| A 398 | <p>Continued From page 100</p> <p>the policy, "Constant Observation, 1:1 Care, and Enhanced Supervision." The letter indicated it would demonstrate Sitter X's "failure to maintain constant observation that, in part, led to patient harm."</p> <p>Review of the above letter, under the heading, "Failure to Maintain Constant Observation of a Patient, indicated, "When [Sitter X] arrived at room 19, [Sitter X] acquired a Workstation on Wheels (WOW) for documentation purposes and set up the WOW outside of the room with your back to the door and the observation window in the door. [Sitter X] failed to obtain a n95 respirator as part of your personal protective equipment (PPE) prior to starting your assignment. [Sitter X] failed to perform an environment care check of the room prior to sitting for the patient to make sure the room did not have any items that patient [16] could have used to harm himself, staff, or others. During [Sitter X's] constant observation assignment, [Sitter X] had [Sitter X's] back to the patient ... and [Sitter X] failed to chart the patient's status in patient [16]'s Electronic Medical Record (EMR). All of these actions violate County policies. Approximately one hour [6:39 p.m.] into [Sitter X's] constant observation assignment, [Patient 16] pulled out his IV, opened the door to his room, and proceeded to walk in front of [Sitter X] and down the hallway. Despite the importance of [Sitter X's] constant observation role, [Sitter X] failed to notice that the patient had left the room ... Once [Patient 16] was finished using the public restroom, [Sitter X] escorted him back to room 19, closed the door, moved the WOW in front of the door of the room, abandoned the patient ([Sitter X's] only assignment), and left him</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 101</p> <p>unattended. Because [Sitter X was] not present, [Sitter X] could not observe [Patient 16] even though [Patient 16] was a 5150/constant observation patient. Prior to leaving [Patient 16] unattended, [Sitter X] did not hand off [Sitter X's] constant observation responsibilities to another staff member of the ED in direct violation of County policy. As [Sitter X was] not there, [Patient 16] simply opened the door to his room and left for the second time. [Patient 16] then ran out of the ED, left the hospital, ran to an adjacent building, and jumped off a high floor. [Patient 16] returned to [this hospital] as a trauma patient with critical injuries."</p> <p>Review of the hospital's policy, "5150 (or 72 Hour Hold)," dated 1/30/2019, indicated, "A 1:1 sitter is required for any patient held as 5150 DS [danger to self] or DO [danger to others]."</p> <p>Review of the facility's policy, "Suicide/Safety Precautions and Care of the Patient in Non-Behavioral Health Areas," dated 6/24/20 indicated to ensure a safe environment free from any potentially harmful items or environmental conditions. The policy also indicated documentation shall include the means provided by the staff to reduce potential hazards in the patient's environment.</p> <p>Review of the hospital's policy, "Constant Observation, 1:1 Care, and Enhanced Supervision", dated 6/27/2019, intended for all hospital employees, indicated the following:</p> <p>"Constant Observation (CO): Continuous unbroken observation by appropriate staff from a distance of not more than one arm's length. For</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 102</p> <p>agitated and infectious patients, the distance may be increased to two arm lengths or 15 feet for the observer's safety while maintaining a constant view of the patient. CO caregiver (nursing staff) to patient ratio must be 1:1 at all times."</p> <p>"A patient who has expressed suicidal ideation MUST be on CO until a psychiatrist evaluates the patient and determines the patient is no longer a danger to him or herself."</p> <p>"While working a shift as a patient observer/supervisor [sitter], each staff member must ... give report to the patient's nurse before leaving the unit or before performing a task that would prevent them from completing the required supervision ... The staff member must not leave the patient until another staff member is in attendance and a direct report to the relieving staff is given.</p> <p>Review of the hospital's policy, "Chain of Command to Support Safe, Quality Patient Care," dated 11/14/2018 indicated, "Initiating chain of command ensures:</p> <ol style="list-style-type: none"> 1. communication to the appropriate individual to ensure they are aware of the situation; 2. action initiated from the level closest to the event and communication moves through the hierarchy chain as the situation warrants; 3. accountability is maintained when issues are not managed effectively ... " <p>The policy also indicated, "Every employee has the responsibility to make decisions and take actions that support patient, visitor and staff safety. Employees are to initiate the chain of command when: ... any other situations that may</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 398 | <p>Continued From page 103</p> <p>support safe, quality patient care and service ..."</p> <p>3. Review of Patient 10's emergency admission dated 9/17/22 indicated he was admitted to the facility with a diagnosis of Tylenol ingestion, intentional self-harm.</p> <p>Review of Patient 10's order indicated on 9/17/22 at 8:19 p.m. order for neuro checks (neurological examinations, assessment of cognitive and motor responses to determine whether the nervous system is impaired) every four hours and the order was scheduled for 9/18/22 at 12:00 a.m.</p> <p>During a concurrent interview and record review with registered nurse G (RN G) on 9/21/22 at 9:30 a.m., Patient 10's neuro checks flow sheet was reviewed and indicated there was no documentation of neuro checks on 9/18/22 from 12:00 a.m. to 12:00 p.m. RN G acknowledged neuro checks was not done as ordered.</p> <p>Review of the hospital policy, "Provider Orders", dated 4/27/22, indicated to assure the acknowledgement, coordination, and implementation of provider orders, to assure that implementation of provider orders complies with Nursing practice and Care Standards."</p> <p>4a. Review of Patient 13's medication administration dated 9/12/22 indicated Patient 13 received tramadol 50 mg for back pain and with a pain score of 9.</p> <p>During a concurrent interview and record review with RN G on 9/21/22 at 2:10 p.m., Patient 13's pain flow sheet indicated licensed nurse missed the post pain assessment on 9/21/22. RN G stated post pain assessment should be done.</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 398 | <p>Continued From page 104</p> <p>4b. Patient 21 was admitted to the facility on 9/14/22 from Skilled Nursing facility (SNF) due to an unwitnessed fall.</p> <p>Record review on 9/22/22 at 1:36 p.m., indicated Patient 21 was in the emergency room (ED) at 8:12 a.m. with head pain level of "8" on the numeric scale.</p> <p>During a concurrent interview and record review on 9/22/22 at 1:42 p.m. with registered nurse M (RN M), She reviewed Patient 21's ED medication administration record (MAR, a record of medications given), indicated Tylenol 650 milligrams (mg, unit of dose measurement) one tablet by mouth (P.O.) was given at 1:40 p.m. and no documentation that the reassessment was done for the effectiveness of Tylenol as an intervention. Pain assessment was done on 9/14/22 at 2:44 p.m. and Patient 21's pain level was documented as a "7" on the numeric pain scale and no pain management interventions were offered. This scale provides a tool with which a patient can assign a number from 1 to 10 to their level of pain, (0 indicating no pain), (1-3 mild pain), (4-6 moderate pain), 7-10 worst possible pain.</p> <p>Review of the hospital's policy, "Pain Management Standards - Inpatient and Outpatient, dated 10//20/2021, indicated "Patients will be assessed for presence of pain, intensity, history of pain and pain relief. Pain response should be reassessed within 1 hour after administering an as needed medication for pain or reassessment must be documented as to the effect of the intervention and reassessment</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
|--|--|---|---|----------------------|---|
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| A 398 | <p>Continued From page 105 will be entered no later than 1 hour after the intervention.</p> <p>4c. Patient 25 was brought to the emergency department (ED) on 9/6/22 with dizziness and facial pain.</p> <p>During a review of Patient 25's electronic record (record) with Registered Nurse Z (RN Z) on 9/22/22 at 11:16 a.m.. Patient 25's record indicated he had been assessed for pain at 8:03 p.m., giving it a 6 on a scale of 1-10, 10 being the worst pain. Patient 25's record did not indicate any pain medication was given, or even ordered.</p> <p>During an interview with RN Z on 9/22/22 at 11:16 a.m., RN Z stated, Patient 25 had been taken to x-ray for CT scan (x-ray images taken in succession in thin slices to see an almost 3-D image) right after pain assessment at 8:03 p.m. RN Z stated, Patient 25 was not finished with the procedure until 9:46 p.m., then the ED team started the process of transferring Patient 25 to another hospital. RN Z stated, no pain medication was ordered.</p> <p>During a review of the facility's policy and procedure (P&P), titled Pain Management, dated 10/20/21, the P&P indicated, ...All patients have the right to an appropriate pain assessment and management of pai that will be treated promptly, effectively, and for as long as pain persists, by utilizing all available interventions/resources necessary to achieve acceptable pain management. Pain will be assessed and documented. The hospital or clinic shall ensure that pain assessment is performed in a consistent manner that is appropriate to the</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128 | | |
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| A 398 | <p>Continued From page 106 patient.</p> <p>5. Review of Patient 7's medical record indicated he was admitted with multiple diagnoses including dementia with behavior disturbances.</p> <p>During a concurrent interview and record review on 9/22/22 at 9:00 a.m. with Registered Nurse L (RN L) , Patient 7's medical record dated 8/1/22 was reviewed. The orders indicated a remote sitter order dated 8/1/22 with a start time at 2:33 p.m. and discontinuing on 8/4/22 at 4:49 p.m.</p> <p>During a concurrent interview and record review on 9/22/22 at 9:00 a.m. with Registered Nurse L (RN L), Patient 7's medical record indicated no evidence of remote sitter documentation was completed on 8/2/22 between 5 p.m. and 11 pm., on 8/3/22 between 9 a.m. and 2 p.m., on 8/3/22 between 11 p.m. and 8/4/22 6 a.m., and on 8/4/22 between 8am and 3pm. On 8/2/22, 8/3/22, and 8/4/22 documentation for the remote sitter was incomplete on nine occurrences. RN L confirmed the missing documentation for Patient 7.</p> <p>During an interview on 9/22/22 at 3:30 pm Registered Nurse O (RN O) stated remote sitter documentation is every four hours by the Registered Nurse, documentation includes indications and assessments.</p> <p>During a review of the facility's policy and procedure titled, "Continuous visual monitoring of patients using the remote sitter device" dated 6/21, the policy indicated, "Primary bedside nurse responsibility ...Reassess patient at least every four hours for need to continue monitoring</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

PRINTED: 10/26/2022
FORM APPROVED
OMB NO. 0938-0391

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| A 398 | <p>Continued From page 107 with remote sitter device".</p> <p>b. Patient 8 was admitted with multiple diagnoses including altered mental status and delusions.</p> <p>During a concurrent interview and record review on 9/23/22 at 8:15 a.m. with Registered Nurse L (RN L), Patient 8's "1:1 sitter orders," dated 9/19/22 were reviewed. The order indicated a 1:1 sitter order for 9/19/22 with a start time at 5:34 a.m. and discontinuing on 9/19/22 at 10 p.m.</p> <p>During a concurrent interview and record review on 9/23/22 at 8:15 a.m. with RN L, Patient 8's medical record was reviewed, the flowsheet (form that gathers all the important data regarding a patient's condition) indicated there was no sitter documentation completed on 9/19/22 between 3 p.m. and 10:00 p.m. RN L confirmed the missing documentation for Patient 8. Additional review of the flowsheet indicated documentation on 9/19/22 was incomplete at 12:47 p.m., 2 p.m., and 3 p.m., which was confirmed by RN L.</p> <p>During an interview on 9/23/22 at 8:15 a.m., with Registered Nurse O (RNO), RN O stated 1:1 constant sitter documentation is every 1 hour.</p> <p>c. Review of Patient 10's physician order, dated 9/17/22 at 9:15 p.m., indicated 1:1 sitter, danger to self.</p> <p>Review of Patient 10's safety interventions and observation flowsheet indicated missing documentation on 9/17/22 starting at 9:15 p.m. as ordered. The safety interventions and observation flowsheet was not started until</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 108 9/18/22 at 1:26 p.m.</p> <p>Review of Patient 10's nurses note dated 9/17/22 indicated sitter at bedside.</p> <p>d. Review of Patient 11's physician order indicated 1:2 sitter, confusion/delirium, high fall risk, dated 9/18/22 at 10:23 p.m. and 9/19/22 at 6:56 a.m. respectively. The sitter order was discontinued on 9/21/22 at 4:52 a.m.</p> <p>Review of Patient 11's observation flowsheet indicated missing documentations on the following dates and times: On 9/18/22 at 10:00 p.m. and 11:00 p.m.; On 9/19/22 at 7:00 a.m., 8:00 a.m., 9:00 a.m., 11:00 a.m., 12:00 p.m., 1:00 p.m., 2:00 p.m., 3:00 p.m., 4:00 p.m., 5:00 p.m., and 6:00 p.m.</p> <p>During a concurrent interview and record review with the assistant nurse manager H (ANM H) on 9/22/22 at 10:45 a.m., she stated licensed nurses should complete the safety interventions flow sheet every shift and either the licensed nurse or HSA (health services assistant, sitter) should complete the observation flowsheet every hour for any patients with a sitter order. ANM H acknowledged inconsistency with documentation by the licensed nurses and HSA (sitter) for Patient 10 and Patient 11.</p> <p>e. Review of Patient 15's physician order indicated 1:1 sitter, danger to self, dated 9/1/22 at 12:56 p.m. and discontinued on 9/5/22 at 12:06 a.m. The sitter order was resumed on 9/5/22 at 12:27 a.m. until discontinued.</p> <p>Review of Patient 15's observation flowsheet</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

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OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| A 398 | <p>Continued From page 109</p> <p>indicated missing documentation on the following dates and times: On 9/1/22 at 12:00 p.m., 1:00 p.m., 2:00 p.m., 3:00 p.m., 5:00 p.m., 6:00 p.m., 7:00 p.m., 9:00 p.m., 10:00 p.m., and 11:00 p.m.; On 9/2/22 at 1:00 a.m., 2:00 a.m., 3:00 a.m., 5:00 a.m., 6:00 a.m., 9:00 a.m., 10:00 a.m., 11:00 a.m., 12:00 p.m., 2:00 p.m., 3:00 p.m., 5:00 p.m., 6:00 p.m., 7:00 p.m., 9:00 p.m., and 11:00 p.m.; On 9/3/22 at 3:00 a.m., 5:00 a.m., and 7:00 a.m.; On 9/4/22 at 7:00 a.m., 5:00 p.m., 6:00 p.m., and 7:00 p.m. On 9/5/22 at 1:00 a.m., 2:00 a.m., 3:00 a.m., and 7:00 a.m.; On 9/6/22 at 5:00 p.m.; On 9/7/22 at 1:00 a.m., 2:00 a.m., 3:00 a.m., 4:00 a.m., 5:00 a.m., 6:00 a.m., 7:00 a.m., 10:00 a.m., 11:00 a.m., 1:00 p.m., 2:00 p.m., and 3:00 p.m.; On 9/8/22 at 9:00 p.m. and 10:00 p.m.; On 9/10/22 at 9:00 p.m. and 11:00 pm.</p> <p>Review of Patient 15's safety observation flowsheet indicated missing documentation on the following dates: On 9/1/22, 9/5/22, 9/8/22 (morning shift) and on 9/11/22 (night shift).</p> <p>During a concurrent interview and record review with registered nurse I (RN I) on 9/22/22 at 1:40 p.m., she acknowledged Patient 15's observation and safety intervention documentations were missing on the above dates and times.</p> <p>Review of the hospital policy, "Constant Observation, 1:1 Care, and Enhanced Supervision", dated 2/23/22, indicated while working a shift as a patient observer/supervisor, each staff member must document patient is under constant observation or enhanced supervision in patient's record on an hourly basis.</p> <p>6. Review of Patient 45's Medical Record dated</p> | A 398 | (Please see Attachment A, pg. 29-41) | | |

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

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FORM APPROVED
OMB NO. 0938-0391

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| A 398 | <p>Continued From page 110</p> <p>12/2/2021 indicated Patient 45 arrived at the Emergency Department on 12/2/2021 at 5:05 p.m. with the chief complaint of "Suicide Attempt (Mother reports that patient attempted strangulation 11/30/2021, she did not tell anyone until 12/2/21, patient currently denies suicidal ideation. Patient is in a program for anorexia (an eating disorder)."</p> <p>During a concurrent interview and record review on 9/29/22 at 4:10 p.m., with Registered Nurse XX (RN XX), Patient 45's Medical Record dated 12/2/21 was reviewed. The Emergency Department triage note indicated, "Patient was triaged at 5:07 p.m. as a "ED acuity 2" (level-2 patients are very ill and at high risk). Patient was placed in the waiting room. At 7:50 p.m. vital signs (temperature, blood pressure, pulse and breathing rate) were completed, and labs were drawn. There was no evidence of additional assessments until 12/3/21 at 12:07 a.m. that indicated Patient 45 "DNA" (did not answer), "ED Disposition: Eloped". RN XX stated, "Reassessment of waiting room patients by the triage nurse is every two hours and there should be reassessment documentation and vital signs".</p> <p>During a review of the hospital's policy "Department of Emergency Medicine Standards Manual -Assessment" dated 1/27/21, the policy indicated, "Complete vital signs ...shall be obtained on all patients upon admission and every two hours thereafter...".</p> <p>During a review of the hospital's policy "Department of Emergency Medicine Standards Manual -Triage" dated 4/4/19, the policy indicated, "Any patient who is in need of</p> | A 398 | (Please see Attachment A, pg. 29-41) | |
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| A 398 | <p>Continued From page 111 immediate care ...shall be classified as Triage level 1 or 2 and escorted to an appropriate treatment area".</p> <p>Review of the "Emergency Services Index [ESI, triage tool for emergency department care]", 2020 edition, indicated "ESI does not specify timeframes to physician evaluation ... However, it is understood that the level 2 patients should be evaluated as soon as possible".</p> <p>7. Review of Sitter X Emergency Department (ED) Competency dated 10/1/2020 indicated under restraints checklist tasks included verbalizes documentation requirements for enhanced observation, medical, and behavioral restraints. It did not indicate competency on constant observation.</p> <p>Sitter X's ED Competency, dated 7/11/2019, indicated under restraints competency criteria included defines constant observation and enhanced supervision. Both of the competencies listed different checklist task or criteria and did not indicate sitter specific.</p> <p>During a concurrent interview and record review with the director of nursing critical care (DNCC) on 9/26/22 at 10:00 a.m., she stated the ED competency for sitter was not specified in the competency but included under restraints. DNCC stated the restraints and constant observation policy covers the teaching for sitter.</p> <p>Review of the hospital policy , "Constant Observation, 1:1 sitter, and Enhanced Supervision" dated 2/23/22, indicated the following definitions: Constant Observation</p> | A 398 | (Please see Attachment A, pg. 29-41) | |
|-------|--|-------|--------------------------------------|--|

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

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| A 398 | <p>Continued From page 112</p> <p>(CO)-continuous unbroken observation by appropriate staff from a distance of not more than one arm's length. CO caregiver (nursing staff) to patient ratio must be 1:1 at all times. 1:1 Care - is for non-suicidal patients requiring more than enhanced. Enhanced Supervision - frequent checks for patients that are at increased risk for falls or other type of injury.</p> <p>8. During an initial tour observation on 9/20/22 at 10:57 a.m., Patient 21's laboratory kit with butterfly needles and syringe inside the plastic kit was exposed on top of a red sharps container inside her room.</p> <p>During a concurrent observation and interview with clinical nurse BB (CN BB) on 9/20/22 at 10:59 a.m., she confirmed the above observation and stated that butterfly needles, syringe and other sharps inside the laboratory kit should have been disposed inside the red sharp container inside the Patient 21's room.</p> <p>During a concurrent observation and interview with Director of Care Management AA (DCM AA) on 9/20/22 at 11:05 a.m., DCM AA, she acknowledged the above observation and she stated that laboratory kit with butterfly needles and syringe inside the plastic kit should have been disposed properly inside the red sharp container mounted to the wall of Patient 21's room.</p> <p>Review of the hospital's 8/24/22 policy, "Safety: Nursing Units & Clinics" indicated needles and syringes are disposed of by placing in designated</p> | A 398 | (Please see Attachment A, pg. 29-41) | |

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

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| A 398 | Continued From page 113 puncture resistant containers immediately after use are kept inaccessible to unauthorized persons. Review of the hospital's policy, "Infection Prevention Manual- Disposal of needles, syringes, and sharp objects (Sharps)" indicated to establish a policy for the safe disposal of needles, syringes, and other sharps. Puncture resistant sharps containers are for the disposal of potentially sharp itemspuncture-resistant containers approved for needle disposal shall be located as close as possible to the area of use for convenience and safety, e.g., Patient rooms, etc. Wall mounted containers should be mounted at the height indicated by current NIOSH regulations. | A 398 | (Please see Attachment A, pg. 29-41) | | |
| A 405 | ADMINISTRATION OF DRUGS CFR(s): 482.23(c)(1), (c)(1)(i) & (c)(2) (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. (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. (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal | A 405 | (Please see Attachment A, pg. 41-43) | | |

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

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| A 405 | <p>Continued From page 114 and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure the physician order for a medication was written with an indication for use for one patient (Patient 25), when the order for Ondansetron was lacking the indication for its use. This failure could cause the administration of an unnecessary medication.</p> <p>Findings:</p> <p>Patient 25 was in the emergency department on 9/6/22.</p> <p>During a review of Patient 25's electronic record on 9/22/22 at 11:16 a.m., with Registered Nurse Z (RN Z), RN Z stated, Patient 25's electronic record indicated, he had experienced dizziness and facial pain.</p> <p>During an interview on 9/22/22 at 11:16 a.m. with RN Z, RN Z stated, Resident 25 was administered Ondansetron 4 mg (amount of medication, dosage) via IV (intravenous, a small tube placed into a vein to give fluids and medication). RN Z stated, the physician order did not indicate a reason/rationale/indication for the medication, and it should have.</p> <p>During a review of the hospital's policy and procedure (P&P), titled Medication Ordering and Administration, dated 4/27/22, P&P indicated, ...Indications for PRN drugs - To avoid therapeutic duplication, if more than one</p> | A 405 | (Please see Attachment A, pg. 41-43) | |

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

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| A 405 | Continued From page 115 medication is ordered for the same indication, the medications will be ranked by order of administration preference. Documentation within the medical record must support, by diagnosis, condition, or indication for use, each medication that is ordered. | A 405 | (Please see Attachment A, pg. 41-43) | | |
| A 407 | <p>VERBAL ORDERS FOR DRUGS CFR(s): 482.23(c)(3)(i)</p> <p>If verbal orders are used, they are to be used infrequently.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review the facility failed to ensure verbal orders for Patient 10 was authenticated by the prescribing physician within 48 hours as per hospital policy. This failure had the potential for increased risk of physician order miscommunication.</p> <p>Findings:</p> <p>Review of Patient 10's physician orders, dated 9/17/22 indicated 1:1 sitter and suicide precautions. The orders was entered as a verbal order by a licensed nurse.</p> <p>During a concurrent interview and record review with registered nurse G (RN G) on 9/21/22 at 2:10 p.m., RN G stated nursing should have entered the order above and it did not need to be signed off by a provider. RN G stated since the order for Patient 10 was entered as verbal, provider should sign off the order. RN G was not able to provide documentation the above orders were signed off by a provider.</p> <p>Review of the hospital's policy, "Acceptance of</p> | A 407 | (Please see Attachment A, pg. 43-44) | | |

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| A 407 | Continued From page 116 Verbal Orders", dated 9/12/2018, indicated all verbal orders and telephone orders must be dated, timed, and authenticated by the ordering practitioner or by another practitioner who is responsible for the care of the patient at the next available opportunity, but no later than within 48 hours. | A 407 | (Please see Attachment A, pg. 43-44) | | |
| A 440 | CODING AND INDEXING OF MEDICAL RECORDS CFR(s): 482.24(b)(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to have an accurate system of coding and indexing of medical records and did not allow for timely retrieval of medical records to support medical care evaluation studies. This failure had the potential to result in ineffective quality assurance and performance improvement measurement efforts for the facility. FINDINGS: During a review and concurrent interview of the HIM Director (HIMD) on 9/22/22, Patient 1's (Pt 1) inpatient electronic health record (E.H.R.) encounter for August 2022 was viewed on a computer screen. Pt 1's medical record showed an admission on 8/12/22 via the Emergency Room and the Event Management screen of the medical record showed a discharge on 8/17/22 (screen shot #1). Pt 1 was admitted as a "5150 | A 440 | (Please see Attachment A, pg. 44-48) | | |

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

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| A 440 | <p>Continued From page 117</p> <p>hold" (allows a person with a mental challenge to be involuntarily detained for a 72-hour psychiatric hospitalization) with self-inflicted stab wounds to his abdomen using a four inch knife. Following Pt 1's emergency surgery to repair the abdominal wounds on 8/12/22, the attending physician/surgeon had requested a psychiatric consult. The medical record included a Death Summary documenting a time of death at 9:12 p.m. on 8/17/22 with "Diagnoses listed as the cause of death: Patient broke window of his room with a chair and fell from a height (4th story hospital room)".</p> <p>During the review, a listing of the hospital's July to August 2022 discharges and expirations (Discharge & Expiration List) was requested on 9/22/22 and electronically received from the facility on 9/23/22. The list did not include Pt 1 as an expiration.</p> <p>During a second record review of Pt 1's E.H.R. on 9/27/22 with concurrent interview, the HIMD was asked why Pt 1 was not on the list as an expiration and incorrectly reported as a discharge on 8/17/22, but no explanation was offered. The patient had been admitted on 8/12/12 under a different medical record number. HIMD explained that the correction of a duplicate medical record would not be done until after the discharge of an inpatient per the facility policy and procedure.</p> <p>During a third record review of Pt 1 medical record on 9/29/22, documentation of prior treatment at the facility that had taken place on 7/18/22 and 7/25/22 with a 5150 hold was viewed. Prior medical records which were not in Pt 1's record during his 8/12/22 inpatient stay</p> | A 440 | (Please see Attachment A, pg. 44-48) | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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| A 440 | <p>Continued From page 118</p> <p>would have helped to communicate past medical history and prior treatments to the medical and nursing staff. Pt 1's medical record had not been corrected to include all previous encounters at the facility until 8/21/22 [Contact Originally from a Different Chart] to merge information from the original medical record to inform care providers of history that Pt 1 was "an acute risk for Danger to Self: High". An E.H.R. audit trail was requested and provided by the facility on 9/29/22.</p> <p>During a review of the E.H.R. audit trail (a tracking of the chronological documentation of the documentation entries in the computerized medical record) of Pt 1's E.H.R. showed no efforts by clinical staff to locate or link previous medical records of Pt 1 containing prior medical history.</p> <p>During an interview on 9/28/22 the Director of Nursing Critical Care (DNCC) was asked about the registration process for patients treated in the Emergency Department (ED). DNCC stated that many ED patients were initially registered as "John or Jane Doe" (a placeholder name, later substituted with the real patient's name) and if there was a duplicate medical record from prior treatment at the hospital, the past medical record would be merged with the current record after the patient was discharged.</p> <p>During a review of Pt 1's medical record and concurrent interview with the HIMD on 9/28/22, the coding summaries for Pt 1 and Pt 16 was requested. Among the final diagnostic codes for Pt 1, the code for suicide attempt was not captured which was T14.91 (diagnosis code of the International Classification of Diseases, 10th</p> | A 440 | (Please see Attachment A, pg. 44-48) | | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 10/03/2022 |
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| NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128 | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE | |
| A 440 | <p>Continued From page 119 Revision) and the coding summary also erroneously noted that the code Y92.230 "Patient room in hospital as the place of the external cause" as a diagnosis that was "Present on Admission, POA".</p> <p>During a record review of Patient 16 (Pt 16) on 9/28/22, there was failure to accurately code and index the patient admission of 5/12/21. In a concurrent interview with HIMD regarding Pt 16 on 9/28/22, the timeline of treatment was followed from admission on 5/12/21 at 9:54 p.m. in the Emergency Psychiatric Service (EPS) transferred by ambulance from a sister facility. Pt 16 was on a 5150 hold and suicidal tendency was documented. Due to a positive COVID-19 (highly contagious coronavirus) test result, Pt 16 was transferred from EPS to the hospital E.D., to await an available inpatient psychiatric bed that was in a COVID-19 quarantine area. Pt 16 was on a 1:1 observation status for a 5150 hold along with COVID-19 symptoms which required isolation. While in the Emergency Room, even with 1:1 observation, Pt 16 eloped from the ED having pulled out his IV (intravenous) line and briefly stalled by nursing staff in the ED at 6:49 p.m on 5/13/21. Documentation by Pt 16's nurse (RN-S) mentions the elopemnt.</p> <p>During a review of the hospital's policy and procedure titled "Elopement/Missing Patient", an elopement is "defined within 2 hours from the time of discovery" and specified that measures are "taken to prevent the elopement of any patient from the hospital" with "high risk patient for elopement" and should have been appropriately coded in the indications for disposition status from the licensed facility per</p> | A 440 | (Please see Attachment A, pg. 44-48) | | |

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

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| A 440 | Continued From page 120 state reporting requirements. An elopement of a high-risk patient not found in 10 minutes would activate a hospital wide high alert called "Code Green". No Code Green was documented in the ED notes for Pt 16 on 5/13/21. During a review of the patient lists of elopements from 2021 and 2022 at the ED of the facility, there were 4,334 elopements in the calendar year 2021, and in 2022, 3,985 elopements for two thirds of the current year. | A 440 | (Please see Attachment A, pg. 44-48) | |
| A 449 | CONTENT OF RECORD CFR(s): 482.24(c) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. This STANDARD is not met as evidenced by: The facility failed to ensure that the patient's medical record contained timely information to describe past patient history, patient progress and response to medications and services. This failure was apparent during a recent E.H.R. system downtime and backup business recovery processes for medical record documentation were not available to nursing and medical staff. This failure had the potential to result in missing of clinical information, past medical history, allergies, and medication administration records that would hamper the continuity of care of patients creating patient safety issues. Also the lack of medical records had the potential to create inefficiencies in patient care delivery and repeating of expensive therapies and diagnostic tests. | A 449 | (Please see Attachment A, pg. 48-49) | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 449 | <p>Continued From page 121</p> <p>FINDINGS:</p> <p>During an observation tour of the Med/Surg unit on 9/27/22 with concurrent interview with the HIM Director (HIMD) and the head nurse of the 4th floor Medical/Surgery unit (RN P), the recent regional power failure on 9/6/22 was discussed. Over a three-day period due to hot weather temperatures, the power supply to the facility failed initially for a four-hour period and intermittently through 9/8/22 causing the Electronic Health Record (E.H.R.) system to fail.</p> <p>During the observation of the nursing unit on 9/27/22, the presence of a backup computer was determined to be at the 4E nursing situation with a power source from an emergency power system outlet, that provided access to the E.H.R. of patients so that medication and care documentation could be accessed.</p> <p>During a records review and concurrent interview with RN P on 9/27/22, the manual back-up medical record forms to be used by nurses, physicians, and other staff members during an E.H.R. downtime were requested. Additionally, the facility policy and procedure for business continuity was requested and provided by HIMD. The policy & procedure showing the last update on April 15, 2022, entitled "Business Continuity Access: Policy and Procedure" was provided by HIMD. The policy and procedure on page 28 had a list of documents needed on each nursing unit (Addendum 5- Inpatient Downtime Forms).</p> <p>During the review of policy and procedure and the available forms at the medical/surgical unit, eight medical record documents were provided</p> | A 449 | (Please see Attachment A, pg. 48-49) | |

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 449 | Continued From page 122 for nursing station 4E. The forms indicated that they were last edited in 2005, 2007, 2008, and 2012 and were not representative forms that would be in urgent usage during a failure with E.H.R system outage. The back up paper medical record forms needed to be current and to mirror documentation normally entered in the E.H.R. by nurses and physicians to document patient care. The facility did not provide evidence of preparedness and readiness for an emergency downtime of the E.G. system. According to HIMD, the adoption of the E.H.R. system at the facility was in 2013. The older versions of the back-up paper medical record forms would not be recognizable or usable to current clinical users at the facility. | A 449 | (Please see Attachment A, pg. 48-49) | | |
| A 466 | CONTENT OF RECORD: INFORMED CONSENT CFR(s): 482.24(c)(4)(v) [All records must document the following, as appropriate:] Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent. This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to ensure one patient (Patient 35) gave consent to treatment, when the consent to treatment form was not located in Patient 35's electronic record. This failure had the potential of a patient being treated who did not wish to be treated or informed of the treatment plan. Findings: | A 466 | (Please see Attachment A, pg. 49-51) | | |

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

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| A 466 | <p>Continued From page 123</p> <p>Patient 35 was admitted to the hospital on 11/17/2021.</p> <p>During a review of Patient 35's electronic record on 9/27/22 with Sepsis QI coordinator (QC Y), the electronic record did not indicate that Patient 35 received a copy of the facility's general patient consent to treatment (consent to treatment).</p> <p>During an interview on 9/27/22 at 2:46 p.m., with QC Y, she stated, Patient 35 did not have a copy of consent to treatment signed, it was in a que for admitting department.</p> <p>During an interview on 9/29/22 at 10:02 a.m., with the manager of admitting & ED registration (MA DD), MA DD stated, she does not believe there is a signed form for consent to treatment for Patient 35. MA DD stated, in the emergency department (ED), the admission staff should be going around continually, at least every hour, to get signatures. If the patient is admitted, admission staff usually would get their signature by the next morning. MA DD stated, she was not sure why Patient 35's consent to treatment was not signed. MA DD stated, "Attempts should have been made."</p> <p>During an interview on 9/29/22 at 10:02 a.m., with the computer operator (CO EE), CO EE stated, she did not see the consent to treatment form for Patient 35 in the computer.</p> <p>During a review of the hospital's policy and procedure (P&P), titled Informed Consent, revised 2/13/17, the P&P indicated, ...Patients have the right to decide whether to submit to</p> | A 466 | (Please see Attachment A, pg. 49-51) | |

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

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| A 466 | Continued From page 124 medical treatment ... Informed consent discussion and patient's decision must be documented in the patient's medical record. A signed informed consent form approved by Hospital Administration and the Medical Executive Committee, must be completed and filed in the patient's medical record prior to the procedure or treatment. | A 466 | (Please see Attachment A, pg. 49-51) | |
| A 467 | <p>CONTENT OF RECORD: ORDERS,NOTES,REPORTS CFR(s): 482.24(c)(4)(vi)</p> <p>[All records must document the following, as appropriate:] 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.</p> <p>This STANDARD is not met as evidenced by: The facility failed to have all practitioners' orders, nursing notes, reports of treatment, medication records, and other information necessary to monitor the patient's condition because of an excessive number of duplicate medical records in the electronic health record system, with some delay in timely correction of patient medical records. This failure resulted in missing patient medical history of previous encounters that impacted patient safety, and in at least one case an unfortunate death.</p> <p>FINDINGS: During a review of the facility's EMR Integrity committee minutes on 9/27/22, the Duplicate Rate for medical records in the E.H.R. system</p> | A 467 | (Please see Attachment A, pg. 51-53) | |

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| A 467 | <p>Continued From page 125 was 5.84% for 1/21/22, and 3.95% reported for 3/18/22, against an acceptable target of 2.5% for the facility. For the most recent reporting, it indicated, "Total patients with a potential duplicate: 123,431".</p> <p>During a review of the facility's procedure to Correct Duplicate Medical Record Numbers, with a concurrent interview with HIMD on 9/27/22, it was confirmed that the facility's policy did not allow for correction of the medical record duplications during an inpatient stay, only after the point of discharge for patients.</p> <p>During a review on 9/27/22 with concurrent interview of the HIM Director (HIMD) regarding Patient 1 (Pt 1), the medical record was followed from time of admission on 8/12/22 in the Emergency Department (ED) and transfer for surgery. At the time of ED admission, Pt 1 was on a 5150 hold for 72 hours, with self-inflicted abdominal wounds. The patient had been admitted on 8/12/12 under a new medical record number, although Pt 1 had previously been treated at the facility for psychiatric care. HIMD explained that the correction of a duplicate medical record would not be done until after the discharge of an inpatient per the facility policy and procedure.</p> <p>During the medical record review on 9/27/22, post-operative documentation showed that in lieu of placement on the psychiatric service, Pt 1 was to be placed in a room on the Medical/Surgery unit, 4 East (4E), on 8/12/22. A psychiatric consult on 8/13/22 documented, "Acute risk for danger to self: High" and a psychiatry consult follow up note on 8/14/22 extended the patient to</p> | A 467 | (Please see Attachment A, pg. 51-53) | |
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| A 467 | <p>Continued From page 126</p> <p>a 5250 hold for 14 days with the notation, "Patient poses a high risk for suicide". Also, the Inpatient Psych Initial Consult report of 8/13/22 included documentation that the "Patient states that he was doing well until recently". However, upon review of his other chart (MRN: #####) on 7/16/2022 and 7/25/22 patient had approached ED with suicidal thoughts and plans". Also, Pt 1 had an exposure to COVID-19 (highly contagious coronavirus respiratory disease) and could be agitated and infectious as documented for 8/12/22 in Pt 1 E.H.R. notation requiring "Constant Observation, Enhanced Supervision and a 1:1 Care".</p> <p>During additional record review of Pt 1 on 9/27/22, the medical record documentation by nursing was in contrast to that of the psychiatrist with a post-operative nursing note on 8/12/22 at 10:36 p.m. that indicated, "No current thought or plan of harming self. Needs met, safety maintained". There was an "At-Risk Room Safety Checklist (every shift) documenting nursing responses to "Is furniture secured or heavy enough to prevent harm" with "Met" indicated on 8/12/22, 8/13/22 (X 2), 8/14/22 (X 2), 8/15/22 (X 3), 8/16/22 (4), 8/17/22 (x 2, last recorded at 1600).</p> <p>During an interview on 9/27/22 with the head nurse of the 4 East unit (RN P) the 4E MED STAFFING ASSIGNMENT sheet for 8/17/22 was requested and provided. Pt 1 was assigned to Room 15 A just next to the nursing station on 4 East. The assignment sheet for the 1:1 care by Pt 1's nurse (RN A) did not make any Level of Care references for constant, enhanced or COVID-19 precautions, unlike five other level of</p> | A 467 | (Please see Attachment A, pg. 51-53) | |
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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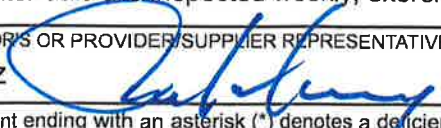
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| A 467 | <p>Continued From page 127 care assignments for other patients on the 8/17/22 assignment sheet.</p> <p>During the record review of Pt 1 on 9/27/22, the Death Summary documented time of death at 9:12 p.m. on 8/17/22 with "Diagnoses listed as the cause of death: Patient broke window of his room with a chair and fell from a height (4th story hospital room)".</p> <p>During the record review on 9/27/22 of a nursing note for Pt 1 on 8/18/22 at 12:27 p.m. included the comment, "He then grabbed a chair, lifted it and started slamming the window to break it. He then jumped up on ledge of the window and jumped out the window".</p> <p>During a second review of Pt 1's medical record on 9/29/22, the document "Contact Originally From a Different Chart in the E.H.R. indicated that the two medical records for Pt 1 were eventually merged on 8/21/22 at 3:08 pm.</p> | A 467 | (Please see Attachment A, pg. 51-53) | |
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| K 000 | <p>INITIAL COMMENTS</p> <p>K3 BUILDING: 01 - Main Hospital, Building S.</p> <p>K6 PLAN APPROVAL:</p> <p>K7 SURVEY UNDER: 2012 EXISTING</p> <p>K12 TYPE OF STRUCTURE: One Story Type II, Fully Sprinklered.</p> <p>The following reflects the findings of the California Department of Public Health, during a Complaint Validation Life Safety Code Survey. The findings are in accordance with 42 Code of Federal Regulations (CFR) §482.41(b)(c)(e), National Fire Protection Association (NFPA) 101 - Life Safety Code, 2012 Edition, and NFPA 99 - Health Care Facilities Code, 2012 Edition.</p> <p>Representing the Department of Public Health: 43380</p> | K 000 | | |
| K 918 | <p>CENSUS: 382</p> <p>Electrical Systems - Essential Electric System CFR(s): NFPA 101</p> <p>Electrical Systems - Essential Electric System Maintenance and Testing</p> <p>The generator or other alternate power source and associated equipment is capable of supplying service within 10 seconds. If the 10-second criterion is not met during the monthly test, a process shall be provided to annually confirm this capability for the life safety and critical branches. Maintenance and testing of the generator and transfer switches are performed in accordance with NFPA 110. Generator sets are inspected weekly, exercised</p> | K 918 | (Please see Attachment A, pg. 53-55) | |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Paul E. Lorenz  | TITLE Chief Executive Officer | (X6) DATE 02/06/2023 |
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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| K 918 | Continued From page 1 under load 30 minutes 12 times a year in 20-40 day intervals, and exercised once every 36 months for 4 continuous hours. Scheduled test under load conditions include a complete simulated cold start and automatic or manual transfer of all EES loads, and are conducted by competent personnel. Maintenance and testing of stored energy power sources (Type 3 EES) are in accordance with NFPA 111. Main and feeder circuit breakers are inspected annually, and a program for periodically exercising the components is established according to manufacturer requirements. Written records of maintenance and testing are maintained and readily available. EES electrical panels and circuits are marked, readily identifiable, and separate from normal power circuits. Minimizing the possibility of damage of the emergency power source is a design consideration for new installations. 6.4.4, 6.5.4, 6.6.4 (NFPA 99), NFPA 110, NFPA 111, 700.10 (NFPA 70) This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the facility failed to maintain the emergency power supply system (EPSS). This was evidenced by a generator that was not permanently mounted and the failure to perform monthly battery testing on the four sealed lead acid generator battery. This affected Building K and could result in a loss of power due to a generator malfunction during an emergency power outage. NFPA 99, Health Care Facilities Code, 2012 Edition. 6.4 Essential Electrical System Requirements - Type 1. | K 918 | (Please see Attachment A, pg. 53-55) | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050038 | (X2) MULTIPLE CONSTRUCTION A. BUILDING 02 - MAIN HOSPITAL B. WING _____ | (X3) DATE SURVEY COMPLETED C 09/21/2022 |
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| NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128 | |
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| K 918 | <p>Continued From page 2</p> <p>6.4.4.1.3 Maintenance of Batteries. Batteries for on-site generators shall be maintained in accordance with NFPA 110, Standard for Emergency and Standby Power Systems.</p> <p>NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition.</p> <p>4.4.3 All equipment shall be permanently installed.</p> <p>8.1* General.</p> <p>8.1.1 The routine maintenance and operational testing program shall be based on all of the following:</p> <p>(1) Manufacturer's recommendations (2) Instruction manuals (3) Minimum requirements of this chapter (4) The authority having jurisdiction</p> <p>8.3.3 A written schedule for routine maintenance and operational testing of the EPSS shall be established.</p> <p>8.3.4 A permanent record of the EPSS inspections, tests, exercising, operation, and repairs shall be maintained and readily available.</p> <p>8.3.4.1 The permanent record shall include the following:</p> <p>(1) The date of the maintenance report (2) Identification of the servicing personnel (3) Notation of any unsatisfactory condition and the corrective action taken, including parts replaced (4) Testing of any repair for the time as recommended by the manufacturer</p> <p>8.3.7.1 Maintenance of lead-acid batteries shall include the monthly testing and recording of electrolyte specific gravity. Battery conductance testing shall be permitted in lieu of the testing of specific gravity when applicable or warranted.</p> | K 918 | (Please see Attachment A, pg. 53-55) | |

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| K 918 | Continued From page 3 Findings: During a tour of the facility, document review, and interview with staff on 9/20/22, the EPSS was observed, and records were requested and reviewed. 1. At 1:05 p.m., a temporary trailer mounted 2000-kilowatt Caterpillar diesel generator was observed connected to the electrical system and parked along the north side of Clove Drive near Building S replacing the permanently installed Cummins 1000 kilowatt diesel generator. The Cummins 1000 kilowatt diesel generator was working but taken offline due to the facility not trusting the generator because of its age. Upon interview, the Utilities Engineer Program Manager and the Facilities-Work Center Manager confirmed the finding and stated the temporary generator was carrying the load for the Cummins 1000 kilowatt diesel generator, which had been taken offline. 2. At 1:37 p.m., the facility failed to provide battery conductance testing records for the four 12-volt, service free batteries that powered the Cummins 1000-kilowatt back-up generator in Building S. Upon interview, the Utilities Engineer Program Manager and the Facilities-Work Center Manager confirmed the finding that conductance testing was not conducted on the batteries, but the batteries were replaced every three years. | K 918 | (Please see Attachment A, pg. 53-55) | |

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| K 000 | <p>INITIAL COMMENTS</p> <p>K3 BUILDING: 01 - Main Hospital, Building S.</p> <p>K6 PLAN APPROVAL:</p> <p>K7 SURVEY UNDER: 2012 EXISTING</p> <p>K12 TYPE OF STRUCTURE: One Story Type II, Fully Sprinklered.</p> <p>The following reflects the findings of the California Department of Public Health, during a Complaint Validation Life Safety Code Survey. The findings are in accordance with 42 Code of Federal Regulations (CFR) §482.41(b)(c)(e), National Fire Protection Association (NFPA) 101 - Life Safety Code, 2012 Edition, and NFPA 99 - Health Care Facilities Code, 2012 Edition.</p> <p>Representing the Department of Public Health: 43380</p> | K 000 | | |
| K 918 | <p>Electrical Systems - Essential Electric System CFR(s): NFPA 101</p> <p>Electrical Systems - Essential Electric System Maintenance and Testing The generator or other alternate power source and associated equipment is capable of supplying service within 10 seconds. If the 10-second criterion is not met during the monthly test, a process shall be provided to annually confirm this capability for the life safety and critical branches. Maintenance and testing of the generator and transfer switches are performed in accordance with NFPA 110. Generator sets are inspected weekly, exercised</p> | K 918 | (Please see Attachment A, pg. 53-55) | |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Paul E. Lorenz  | TITLE Chief Executive Officer | (X6) DATE 02/06/2023 |
|--|---|------------------------------------|

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

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| K 918 | <p>Continued From page 1</p> <p>under load 30 minutes 12 times a year in 20-40 day intervals, and exercised once every 36 months for 4 continuous hours. Scheduled test under load conditions include a complete simulated cold start and automatic or manual transfer of all EES loads, and are conducted by competent personnel. Maintenance and testing of stored energy power sources (Type 3 EES) are in accordance with NFPA 111. Main and feeder circuit breakers are inspected annually, and a program for periodically exercising the components is established according to manufacturer requirements. Written records of maintenance and testing are maintained and readily available. EES electrical panels and circuits are marked, readily identifiable, and separate from normal power circuits. Minimizing the possibility of damage of the emergency power source is a design consideration for new installations.</p> <p>6.4.4, 6.5.4, 6.6.4 (NFPA 99), NFPA 110, NFPA 111, 700.10 (NFPA 70)</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the facility failed to maintain the emergency power supply system (EPSS). This was evidenced by a generator that was not permanently mounted and the failure to perform monthly battery testing on the four sealed lead acid generator battery. This affected Building K and could result in a loss of power due to a generator malfunction during an emergency power outage.</p> <p>NFPA 99, Health Care Facilities Code, 2012 Edition. 6.4 Essential Electrical System Requirements - Type 1.</p> | K 918 | (Please see Attachment A, pg. 53-55) | | |

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| K 918 | <p>Continued From page 2</p> <p>6.4.4.1.3 Maintenance of Batteries. Batteries for on-site generators shall be maintained in accordance with NFPA 110, Standard for Emergency and Standby Power Systems.</p> <p>NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition.</p> <p>4.4.3 All equipment shall be permanently installed.</p> <p>8.1* General.</p> <p>8.1.1 The routine maintenance and operational testing program shall be based on all of the following:</p> <p>(1) Manufacturer's recommendations (2) Instruction manuals (3) Minimum requirements of this chapter (4) The authority having jurisdiction</p> <p>8.3.3 A written schedule for routine maintenance and operational testing of the EPSS shall be established.</p> <p>8.3.4 A permanent record of the EPSS inspections, tests, exercising, operation, and repairs shall be maintained and readily available.</p> <p>8.3.4.1 The permanent record shall include the following:</p> <p>(1) The date of the maintenance report (2) Identification of the servicing personnel (3) Notation of any unsatisfactory condition and the corrective action taken, including parts replaced (4) Testing of any repair for the time as recommended by the manufacturer</p> <p>8.3.7.1 Maintenance of lead-acid batteries shall include the monthly testing and recording of electrolyte specific gravity. Battery conductance testing shall be permitted in lieu of the testing of specific gravity when applicable or warranted.</p> | K 918 | (Please see Attachment A, pg. 53-55) | |
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