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C 000	INITIAL COMMENTS The Oklahoma State Department of Health conducted a Federal complaint survey (OK00052658) at Memorial Hospital of Texas County in Guyman, Oklahoma on 09/27/18, 09/28/18, 10/08/18 and 10/09/18. The following Condition level deficiencies were cited: §485.618 Condition of Participation: Emergency Services §485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review Standard level deficiencies were also cited as a result of the survey. The following abbreviations may be found within this document: CEO = Chief Executive Officer CNO = Chief Nursing Officer COO = Chief Operating Officer ED = Emergency Department EMS = Emergency Medical Service MSE = Medical Screening Examination TPA = Tissue Plasminogen Activator (clot-buster)	C 000		
C 200	EMERGENCY SERVICES CFR(s): 485.618 The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients. This CONDITION is not met as evidenced by: Based on record review and interview, the hospital failed to provide appropriate emergency	C 200		

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

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C 200	Continued From page 1 services and interventions to meet the emergency needs of patients according to current standards of practice as evidenced by: I. one (Patient #23) of three patients with possible stroke who arrived via EMS (Emergency Medical Services) and was sent to another hospital from the hospital's ambulance bay due to no availability of Activase (TPA [Tissue Plasminogen Activator, also known as the "clot-buster"]), without physical evaluation, diagnostic imaging, laboratory studies, and nursing assessment. II. two (Patient #3 and 5) of seven suicidal patients who presented to the emergency department (ED) and did not receive a mental health evaluation through an available contracted telemedicine service to determine the safety of discharge to self or parent's custody for transfer to mental health facility for further treatment. III. one (Patient #6) of two patients who presented with a rattlesnake bite was not assessed prior to discharge to determine stability and current injury status, recommended observation, and anti-venom medication administration (due to unavailability) per hospital policy. IV. one (Patient #10) of two pediatric patients who presented to the ED on three different times with worsening complaints of fever, abdominal pain, and nausea/vomiting with no laboratory studies or diagnostic imaging ordered. These failed practices had the likelihood to:	C 200		

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I. cause injury, delay in care, and worsening of health condition due to lack of early intervention for one (Patient #23) of three patients who presented to the ED with possible stroke via EMS.

II. cause serious harm to two (Patient #3 and 5) patients who presented to the ED with suicide attempts and were transferred through a private vehicle to a mental health facility for further treatment without mental health evaluation and increased risk to patient safety for all suicidal patients who seek treatment in the ED.

III. result in worsening of the health condition for one (Patient #6) patient who presented to the ED with a rattlesnake bite and was not provided assessment, observation, and treatment per hospital policy and standards of practice.

IV. result in worsening health condition and serious harm for one (Patient #10) pediatric patient who presented to the ED with repeated complaints of fever, abdominal pain, and nausea/vomiting with no evidence of laboratory or diagnostic studies ordered per standards of practice.

Findings:

I. Stroke Patients

A review of hospital policy titled "Emergency Medical Screening Examination and Stabilizing Treatment, dated 03/18/18" showed, the hospital campus included physical areas and structures adjacent to the hospital within 250 yards of the hospital...Capabilities included availability of

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equipment, supplies, and routine ancillary (support services such as laboratory, radiology, and pharmacy) services ... patient should be assessed upon arrival for prioritization and determine whether EMS was able to monitor patient's condition appropriately if an immediate medical screening examination (MSE) was not able to be performed.

A review of hospital policy titled "Scope of Service/Plan of Care, dated 01/13/17" showed, patients who presented to the hospital's ED should receive an MSE that included all necessary labs, diagnostic testing, and services within the capabilities of the hospital in order to reach a diagnosis.

A review of hospital document titled "Activase log 09/01/17 through 09/28/18" showed four patients (Patient #1, 2, 25, and 26) had received Activase on the following dates: 09/07/17, 10/08/17, 05/15/18, and 05/25/18. The hospital was not able to provide evidence of an order and receipt between the time period of 05/25/18 to 10/11/18 for the purchase of Activase to show the availability of the medication when Patient #23 arrived on 06/03/18.

A review of an untitled hospital document showed the last purchase date for a package of two 100mg vials of Activase was on 09/07/17.

Review of document titled "Fire Department EMS Incident Report, dated 06/03/18" showed, EMS crew were dispatched at 2:23 pm, to Patient #23's

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residence and arrived on scene seven minutes later at 2:30 pm. At 2:36 pm, EMS crew notified the hospital of positive stroke scale. EMS crew loaded the patient and departed the scene at 2:54 pm, arriving at hospital at 3:07 pm. EMS crew were notified that hospital did not have Activase available. EMS crew notified Staff R that hospital had no Activase available and decision was made to transport patient via air ambulance to next closest acute stroke ready hospital in Texas.

Review of hospital document titled "RM Log Incident with EMS, dated 06/03/18" showed the following:

*"EMS called into ED for positive stroke scale to prepare for head CT" ...Staff S (ED physician) instructed nursing staff to notify EMS the hospital did not have Activase. EMS was notified at the same time they arrived in the ED ambulance bay.

*Incident was entered on 06/03/18 at 5:08 pm, by Staff T (ED RN).

*Incident was reviewed multiple times by Staff F (Manager of Quality/Risk Management) on 06/14/18, 06/25/18, 06/27/18 and no analysis, interventions, or outcomes were documented.

*Staff U (peer review) noted on 06/28/18, Staff S (ED physician on duty on 06/03/18) reported he/she had been made aware of the event and was concerned. It was noted the patient was "in fact in the ED ambulance bay before EMS was alerted there was no Activase in the hospital".

On 09/28/18 at 10:50 am, during a tour of the

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pharmacy surveyors observed a box containing two 100mg vials of Activase in the pharmacy. Staff F was not able to identify when the Activase was purchased or determine how long the box of Activase had been available at the hospital.

On 09/27/18 at 3:44 pm, Staff R (EMS Director) stated, he/she was notified by the EMS crew on arrival at the hospital there was no Activase available. Staff R stated, the EMS crew were on scene approximately 23 minutes and the hospital had "ample time" to notify the EMS crew there was no Activase available. He/she stated, the patient remained in the ambulance and the physician did not evaluate the patient.

On 09/28/18 at 9:30 am, Staff I stated, his/her role included taking radio calls from EMS. Staff I stated, there had been a time when EMS arrived in the ambulance bay and EMS was told they needed to go someplace else because the hospital did not have something. Staff I reported, he/she was the one who notified EMS the hospital did not have Activase on the day of the event.

II. Suicidal Patients

A review of hospital policy titled "Emergency Medical Screening Examination and Stabilizing Treatment, dated 03/18/18" showed ...A psychiatric emergency would be when a patient was a danger to him/herself or others ...patient who presented to the ED for a condition addressed through a pre-arranged community plan such as psychiatry an MSE would be performed and treatment initiated prior to transfer

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C 200	Continued From page 6 of patient pursuant to community plan. A review of hospital policy titled "Patient Awaiting Psychiatric Evaluation, dated 12/28/16" showed the patient should be evaluated and the need for psychiatric evaluation determined. Review of a hospital document titled "Telemedicine Mental Health Access Agreement, dated 01/14/14" showed, a mental health facility would provide licensed mental health professionals to perform telemedicine mental health consultations for patients presenting to the hospital. Review of document titled "Managing Suicidal Patients in the Emergency Department, dated 02/16" from the Annuals of Emergency Medicine showed a suicide risk assessment helped to determine appropriate treatment for suicide patients ...small percentage of patients with suicidal ideation or behaviors may be managed in the ED without a mental health evaluation and discharged home ...patients who tend to be the lowest risk are those with no suicide plan or intent, no prior attempts, mental illness, substance abuse, and/or agitation or irritability. Review of document titled "Suicide Assessment Five-step Evaluation and Triage for Mental Health Professionals, dated 2009" from the Suicide Prevention Resource Center showed determination of suicide risk level included four factors: risk factors, protective factors, suicide inquiry and interventions. High risk for suicide	C 200		

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included an acute precipitating event, potentially lethal suicide attempt or persistent ideation with intent or rehearsal. These patients should be admitted unless there was a significant change in suicide risk. Patients determined to be a moderate suicide risk usually have multiple risk factors, and present with suicidal ideation and plan, but generally no intent or behavior. Depending on the identified risk factors, patients with moderate suicide risk may need to be admitted.

Review of document titled "Caring for Adult Patients with Suicide Risk: A Consensus Guide for Emergency Departments" by the Suicide Prevention Resource Center showed after initial suicidal risk screening a more thorough secondary screening that provides disposition decisions for patients with suicidal ideations should be performed. The screen includes six questions that include thoughts of suicide, suicide intent, past suicide attempts, past mental health issues or issues that affect ability to do things in life, substance abuse issues, and behavioral issues. A mental health professional should be consulted in the ED if a patient answers "yes" to any of the questions for further evaluation, including a comprehensive suicide risk assessment.

Patient #3 was a 17 year old female, who presented to the ED at 1:21 am, via EMS following ingestion of Fluoxetine (Prozac) and Tylenol approximately three hours prior to arrival. Review of Patient #3's medical record showed:

*Suicide assessment identified suicide ideation,

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suicide attempt, feelings of hopelessness and despair and a depressed mood.

*Initial physician assessment performed at 1:45 am, noted overdose was patient's second attempt. Patient was lethargic but arousable. Physician's plan was to repeat Acetaminophen level at nine hours post ingestion and at 6:00 am.

*Initial labs at 1:30 am, showed critical Acetaminophen level at 32 ug/mL (normal 13-30 ug/mL), ALT (Alanine Aminotransferase [blood test to evaluate liver function]) 57 (normal 8-34 IU/L). Acetaminophen level at 5:33 am, was 11 ug/mL.

*Medical Necessity for Air/Ground Transport was completed by physician stating a need for a higher level of care requiring a psychiatric physician specialist that was not available at the hospital.

*Transfer Request/Consent was completed and signed by physician, and noted benefits of transfer to include psychiatric specialist availability to meet the needs of the patient and identifying the patient stable to transfer.

*At approximately 6:00 am, there was a change of shift in ED physicians.

*There was no re-assessment by the oncoming ED physician and no mental health consultation or evaluation obtained via telemedicine.

*At 6:36 am, ED physician discharged patient to home in care of foster parent with instructions "strongly recommend contact place where you had counseling earlier this year and talk with

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them about how you are feeling, what is happening in your life."

* ED physician's final diagnosis was anxiety disorder.

Patient #5 was a 14 year old female, who presented to the ED via private vehicle with reports of ingesting "a handful of Tylenol" approximately 30 minutes prior to arrival. Review of Patient #5's medical record showed:

*Patient reported having family problems and not living with either parent.

*Diagnosed with depression and ordered medication.

*Patient reported "mom does not care enough to get medication for her". Noted "some messed up things happened to her last summer but would not elaborate".

*Physician noted patient was tearful and admitted to overdose by taking "2 handfuls of Tylenol".

*Labs were ordered including a CBC (complete blood count [measures several components of the blood]), CMP (comprehensive metabolic panel [14 tests that provides information on metabolism, electrolyte and acid/base balance, kidney/liver function and blood glucose]), UDS (urine drug screen [test for the presence of illegal and prescription drugs]), urinalysis and Acetaminophen level. Initial Acetaminophen level was critical at 88 (low = 13, high = 30) and UDS was positive for amphetamines and methamphetamines.

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C 200	Continued From page 10 *No psychiatric assessment performed by ED physician. *No suicide assessment was performed by nursing staff at the time of triage or during the physical assessment. *No documentation in the patient's medical record DHS was notified of the patient's suicide attempt by overdose. *There was no evidence the physician obtained a mental health evaluation via telemedicine to determine the presence of an acute psychiatric medical condition. *Patient was diagnosed with Acetaminophen overdose, was given contact information for two psychiatric facilities to follow up with and discharged home with her mother. On 10/10/18 at 8:28 am, Staff P (ED RN) stated, the hospital did have a telemedicine contract with a psychiatric facility to perform mental health evaluations. Staff P stated, the process was to contact the telemedicine site after a suicidal patient was "medically cleared". Staff P stated, "a patient may be suicidal but the ED physician may decide the patient does not need a psychiatric evaluation and discharge them". On 10/10/18 at 9:08 am, Staff Q stated, staff asked the physician why the Patient #5 was being discharged home with her mother. Staff Q stated, the physician said "the patient was an adolescent and her mother could take her." Staff	C 200		

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Q stated, the patient did not have a mental health evaluation at the hospital prior to discharge. Staff Q stated that in his/her experience suicidal patients had received a mental health evaluation prior to discharge from the ED.

On 10/10/18 at 11:59 am, Staff G (Chief of Staff and Medical Director of the ED) stated, the hospital had issues in the ED regarding the quality of care provided to patients by ED physicians. Staff G stated, patients who presented to the hospital with suicidal ideation or suicide attempts should receive a mental health evaluation. Staff G stated the hospital had a telemedicine agreement for mental health services available for such consultations.

III. Rattlesnake Bites

Review of hospital policy titled "Snake Bite, dated 03/18/18" showed, treatment for known rattlesnake bites should include wound care, observation for four to six hours, and discharge home if there was no development of clinical signs. The policy fails to clearly identify the treatment and disposition of the patient when there were development of clinical signs and symptoms such as swelling, erythema, ecchymosis, lab abnormalities, and other non-life threatening symptoms. Policy failed to identify criteria of a "wet" snake bite and when to initiate orders for management of patients with wet snake bites.

Review of hospital document titled "Emergency Department Orders for Snake-Bite Patients (Wet

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Bite) Adult/Pediatric, undated" showed, labs should be obtained including CBC with platelet count, PT/INR (PT = prothrombin time a test that helps to detect and diagnose bleeding or clotting disorders, INR = international normalized ratio a test that measures the time it takes the blood to clot), PTT (partial thromboplastin time a test that assesses the body's ability to form blood clots), Fibrinogen, CMP, and urinalysis. Intravenous (IV) access should be obtained and Normal Saline or Lactated Ringer fluid bolus administered. Mark with a permanent marker from the distal edge of the fang to the leading edge of the swelling, and date and time it. Administer Crofab (anti-venom) immediately.

Review of hospital document titled "Grievance Process Checklist and attachments, dated 04/12/18" showed, a complaint was initiated by the quality/peer review personnel due to a concern regarding the care Patient #6 received in the ED. Findings showed, the standard of care was not met for the care provided to Patient # 6 for the treatment of the rattlesnake bite.

Review of hospital document titled "Continuous Quality Improvement - Patient Complaints and Grievances, dated 04/12/18" showed, the outcome of the quality review regarding Patient #6 was an "extremely unexpected" practice that "could have (or did) contribute to patient injury". Medical record was forwarded for medical record by ESS (ED medical staffing group) for peer review.

Review of untitled hospital document from Jim

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Knecht DO, regarding the review of Patient #6's medical treatment in the ED. His review noted there was no significant change in the patient's condition during the approximately two hours she was in the ED. He noted the patient was sent to Amarillo the next morning by her primary care physician for treatment with the anti-venom. His conclusion was two hours of observation with normal vital signs, normal labs and minimal edema met the "standard for reasonable care".

Review of document titled "Envenomations: Initial Management of Common U.S. Snakebites, dated 06/23/17" by the Academic Life of Emergency Medicine showed labs should include urinalysis, creatine kinase, fibrinogen, PT/INR, PTT, liver function tests, chemistry panel and complete cell count ...signs of envenomation include inflammation such as pain, heat, and redness. Systemic signs may include hypotension, vomiting, coagulopathy (elevated PT, decreased fibrinogen, thrombocytopenia), diarrhea, or angioedema. Patients should be monitored for a minimum of 8 to 12 hours and repeat of labs prior to discharge even for those that show no immediate signs of envenomation.

Patient #6 was a 67 year old female, who arrived in the ED at 7:31 pm, via EMS with complaints of a rattlesnake bite one hour prior to arrival. Review of Patient #6's medical record showed:

*Elevated vital signs: heart rate 117, respirations 22, and blood pressure 167/81

*Nursing assessment noted redness, bruising, tenderness, and warmth of the foot, snakebite marked. Patient denied pain.

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C 200	Continued From page 14 *ED physician assessment noted one fang mark on dorsum right foot with minimal swelling. *At 7:53 pm, ice packs were provided and placed around the patient's foot due to swelling. Assessment failed to identify the amount of swelling. *Patient stated she did not want pain medication at 8:03 pm. There was no documentation of an assessment of the patient's pain to determine if the patient had pain. *Labs were obtained including a CBC, CMP, PT/INR, and PTT. There were no abnormalities. *Triple antibiotic ointment was applied to the bite and the patient was discharged to home at 9:20 pm, approximately 1 hour and 50 minutes after admission. *Prior to discharge there was no evidence physician or nursing staff performed a re-assessment to determine the patient's swelling, redness, bruising, warmth and tenderness to the foot remained stable and there was no increase. On 10/10/18 at 11:59 am, Staff G (Chief of Staff and Medical Director of the ED) stated, he/she was aware the hospital did not have anti-venom at one time resulting in a patient being sent to another hospital. Staff G stated, it was a concern the hospital did not have anti-venom. Staff G stated, he/she was not aware what happened but he/she thought "they were going to make sure they were not short anymore."	C 200		

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C 200	Continued From page 15	C 200		

On 10/10/18 at 1:22 pm, Staff C stated, he/she "was furious" about Patient #6's care in the ED because the hospital did have anti-venom and steroids but "they did not do anything for the patient". Staff C stated the physician who performed the case review "did the same thing before".

IV. Pediatric Patients

A review of hospital policy, "Scope of Service/Plan of Care: Emergency Department", revision date 01/13/17 showed the patient population served by the ED consisted of newborn, pediatric, adolescent, adult and geriatric patients requiring or seeking medical care. Support services included but were not limited to clinical laboratory studies and x-rays that were to be provided to the patient in a timely manner.

A document, "Case Review Form" 05/09/18, showed the form was to be utilized as part of the peer-review process established by the hospital's medical staff bylaws. The conclusion of the review of Patient #10's medical care in the ED showed "there were several findings in the history and physical examination that should have prompted a more thorough evaluation in the emergency department. Treatment did not meet standard of care." The document also showed on 02/08/18, the patient was transferred from a primary care provider's clinic to another facility and underwent surgery for pyloric stenosis.

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Patient #10 was a 27 day old infant, who was brought to the ED on three different occasions with complaints of vomiting, constipation and jaundice. Review of Patient #10's medical record showed the following:

*Patient was in the emergency department on three occasions from 01/29/18 to 02/08/18 with complaints of vomiting, constipation, jaundice (yellowing of the yes caused by elevated liver enzymes, which is an indication of malabsorption of nutrients).

*On 01/29/18 at 17 days old, patient was brought to the ED by his/her mother with complaints of throwing up after feeding. The ED provider documented a normal physical exam. There was no evidence the ED physician ordered labs, diagnostic imaging, or provided medications prior to patient discharge. The patient's weight was documented in the nurse's notes as 3.81 kg.

*On 02/05/28 at 24 days old patient, was brought to the ED by his/her mother with reports of continued vomiting, yellow tinted eyes, "jaundice tint to the skin," and blood in the urine. The ED provider documented "no mass, liver margin palpable". The ED provider did not address reports of blood in patient's urine. The patient's weight was documented in the nurse's notes as 3.45 kg. There was no evidence the ED physician ordered labs, diagnostic imaging, or provided medications prior to discharging patient home.

*On 02/08/18 at 27 days old patient, was brought to the by his/her mother with reports of continued vomiting and no bowel movement for five days. The ED provider documented "normal physical exam". A glycerin suppository was administered.

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C 200	Continued From page 17 The provider documented the patient's weight at 3.45 kg, there was no documentation of weight in the nurse's notes. There was no evidence the ED physician ordered labs or diagnostic imaging and completed prior to patient being discharge home On 10/10/18 at 1:30 pm, Staff B stated, "we decided the contracted ED physician company should address these practices dealing with quality, we pulled records, we looked at census, we addressed concerns daily with them, there isn't documentation of those calls." Staff C stated, in regards to Patient #10 "the lack of care from the doctors was identified". Staff C stated the provider "had to go through training on pyloric stenosis" (the facility was unable to provide documentation of training). On 10/10/18 at 11:59 am, Staff G (Chief of Staff and Medical Director of the ED) stated, the hospital had issues in the ED regarding the quality of care provided to patients by ED physicians. Staff G stated, he was aware the ED physicians had problems dealing with pediatric patients. Staff G stated, another provider had notified him of Patient #10 and he had agreed the standard of care in the ED had not been met.	C 200		
C 330	PERIODIC EVALUATION & QA REVIEW CFR(s): 485.641 Periodic Evaluation and Quality Assurance Review	C 330		

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C 330	Continued From page 18 This CONDITION is not met as evidenced by: Based on record review and interview, the hospital failed to ensure that a functioning Quality Assessment and Performance Improvement (QAPI) program: I. was on-going and included executive and leadership roles and responsibilities for evaluating the quality of care provided in the ED, identifying safety expectations using measurable indicators which identified and reduced patient safety issues, medical errors and adverse outcomes through analyzing causes, implementing preventive actions plans, measuring outcomes for effectiveness and communicating lessons learned as evidenced by the lack of discussion in four of four "Super Committee" meetings from 09/06/17 to 06/27/18, three of three Medical Staff Committee meetings from 06/13/17 to 01/16/18, four of four Medical Executive Committee meetings from 04/04/17 to 01/23/18, three of three Board of Trustees (Governing Body) meetings from 01/24/18 to 08/08/18 and 16 of 16 Special Board of Trustee Committee meetings from 02/15/17 to 08/08/18 for: (Refer to Tag (C-0336) a. one (Patient #23) occurrence reviewed 1/15/18 to 09/15/18 that showed the ED's failure to provide a physical evaluation, diagnostic imaging, laboratory studies, and nursing assessment to a possible stroke patient who arrived via EMS prior to sending the patient to another hospital in Texas due to having no availability of Activase.	C 330		

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b. one (Patient #5) occurrence reviewed 1/15/18 to 09/15/18 that showed the ED's failure to obtain a mental health evaluation and contacting DHS (Department of Human Services) prior to discharging a pediatric patient with suicide attempt and suicidal ideations for transfer to a psychiatric facility through a private vehicle.

c. one (Patient #6) of two occurrences reviewed 1/15/18 to 09/15/18 that showed the ED's failure to follow hospital policy and standards of practice to include recommended observation, assessment prior to discharge, and the availability/administration of anti-venom.

d. two (Patient #8 and 10) of two occurrences reviewed 1/15/18 to 09/15/18 that showed the ED's failure to evaluate, manage, and treat pediatric patients according to current standards of practice.

II. was implemented and formulated risk reduction strategies to reduce patient safety, medical errors and adverse events identified from occurrences and grievances were addressed through the QAPI program. (Refer to Tag C-0342)

III. was implemented so that data was collected to demonstrate the effectiveness of corrective action(s) from risk reduction strategies for medical errors, patient safety, and adverse events. (Refer to Tag C-0343)

These failed practices:

a. had the likelihood for increased risk for worsening health conditions, delays in care, injury

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C 330	Continued From page 20 to self or others, and adverse health outcomes related to the lack of Quality and Risk Management staff's failure to investigate, and analyze occurrence reports, identify preventative action plans, and report findings to a designated Quality Improvement Committee, the Medical Staff and Medical Executive Committees, and the Board of Trustees. b. resulted in deficient occurrence reporting by the Quality/Risk Manager to the "Super Committee" and no evidence of reporting to the Medical Staff and Medical Executive Committees and the Board of Trustees. Therefore, executive committees lacked sufficient information to make informed decisions related to the provisions of quality and safe patient care.	C 330		
C 336	QUALITY ASSURANCE CFR(s): 485.641(b) The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that -- This STANDARD is not met as evidenced by: Based on record review and interview, the hospital failed to ensure a functioning Quality Improvement Program was implemented that included executive and leadership roles and responsibilities for evaluating the quality of care provided by the hospital, identifying safety expectations using measurable indicators which identified and reduced patient safety issues, medical error and adverse outcomes through	C 336		

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analyzing causes, implementing preventive actions plans, measuring outcomes for effectiveness and communicating lessons learned as evidenced by the lack of discussion in four of four "Super Committee" meetings from 09/06/17 to 06/27/18, three of three Medical Staff Committee meetings from 06/13/17 to 01/16/18, four of four Medical Executive Committee meetings from 04/04/17 to 01/23/18, three of three Board of Trustees (Governing Body) meetings from 01/24/18 to 08/08/18 and 16 of 16 Special Board of Trustee Committee meetings from 02/15/17 to 08/08/18 for:

a. one (Patient #23) occurrence reviewed 1/15/18 to 09/15/18 that showed the ED's failure to provide a physical evaluation, diagnostic imaging, laboratory studies, and nursing assessment to a possible stroke patient who arrived via EMS prior to sending the patient to another hospital in Texas due to having no availability of Activase.

b. one (Patient #5) occurrence reviewed 1/15/18 to 09/15/18 that showed the ED's failure to obtain a mental health evaluation and contacting DHS (Department of Human Services) prior to discharging a pediatric patient with suicide attempt and suicidal ideations for transfer to a psychiatric facility through private vehicle.

c. one (Patient #6) of two occurrences reviewed 1/15/18 to 09/15/18 that showed the ED's failure to follow hospital policy and standards of practice to include recommended observation, assessment prior to discharge, and the availability/administration of anti-venom.

d. two (Patient #8 and 10) of two occurrences

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reviewed 1/15/18 to 09/15/18 that showed the ED's failure to evaluate, manage and treat pediatric patients according to current standards of practice.

These failed practices:

I. resulted in the delayed care for two patients (Patient #6 and 23) , worsening health conditions for two patient (Patient #6 and 10), the likelihood for increased risk of injury to self for one patient (Patient #5), and adverse health outcomes for six patients (Patient #5, 6, 7, 8, 10, and 23) related to the lack of Quality and Risk Management staff's failure to investigate, analyze occurrence reports, identify risk reduction strategies, implement corrective action plans, and report findings to a designated Quality Improvement Committee, the Medical Staff and Medical Executive Committees and the Board of Trustees.

II. resulted in deficient occurrence reporting by the Quality/Risk Manager to the "Super Committee" and no evidence of reporting to the Medical Staff and Medical Executive Committees and the Board of Trustees. Therefore, executive committees lacked sufficient information to make informed decisions related to the provisions of quality and safe patient care.

Findings:

Review of hospital policy titled "Quality Manual (QA/PL Plan), revised 04/01/18) showed the following:

-Governing Body, Medical Staff, Hospital

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Administrator/CEO (Chief Executive Officer, Nursing Executive/CNO (Chief Nursing Officer), Quality Representative and Departmental Directors were "responsible and accountable" for the Quality Management Program

-Responsibilities included "development and implementation of an on-going program ...addressing priorities for improved quality of care/treatment/services ...assuring effectiveness of the program ...promoting the use of risk-based thinking and process improvement approach."

-Goals included but were not limited to: improvement of "existing process and functions through a systematic approach"..."high quality patient care through objective care evaluation and other performance assessment activities."

-Design of the program included root cause analysis for "near misses" and facilitate a "systematic examination" for opportunities for improvement ...reporting should be made on a "minimum of a quarterly basis" to the "QAPI committee" ...reporting should include "significant deviations from established standards of practice".

-PACE (Plan, Act, Check and Enhance) should be used to ensure corrective and preventative actions were achieved (Refer to "Corrective and Preventative Action Policy"). On 10/10/18 at 1:22 pm, surveyors requested policy regarding performance improvement initiatives and variance/occurrence reporting, Staff F stated the hospital did not have any policies in relation to these subjects.

-"An unplanned event that did not result in injury,

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illness or damage but had the potential to do so" should be considered a "near miss event". "The organization must collect data, perform root cause analysis (RCA), preserve data (collect), formulate risk reduction strategies and collect data to demonstrate the effectiveness of the corrective action(s)."

I. Stroke

A review of hospital policy titled "Emergency Medical Screening Examination and Stabilizing Treatment, dated 03/18/18" showed, the hospital campus included physical areas and structures adjacent to the hospital within 250 yards of the hospital...Capabilities included availability of equipment, supplies, and routine ancillary (support services such as laboratory, radiology and pharmacy) services ... patient should be assessed upon arrival for prioritization and determine whether EMS was able to monitor patient's condition appropriately if an immediate MSE was not able to be performed.

A review of hospital document titled "Activase log 09/01/17 through 09/28/18" showed four (Patient #1, 2, 25, and 26) patients had received Activase on the following dates: 09/07/17, 10/08/17, 05/15/18 and 05/25/18. The hospital was not able to provide evidence of an order and receipt between the time period of 05/25/18 to 10/11/18 for the purchase of Activase to show the availability of the medication when Patient #23 arrived on 06/03/18.

A review of an untitled hospital document showed the last purchase date for a package of two 100mg vials of Activase was on 09/07/17.

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C 336	Continued From page 25 On 09/28/18 at 10:50 am, during a tour of the pharmacy surveyors observed a box containing two 100mg vials of Activase in the pharmacy. Staff F was not able to identify when the Activase was purchased or determine how long the box of Activase had been available at the hospital. Review of hospital occurrence titled "RM Log Incident with EMS, dated 06/03/18" was entered on 06/03/18 at 5:08 pm by Staff T (ED RN) and showed the following: -"EMS called into ED for positive stroke scale to prepare for head CT" ...Staff S (ED physician) instructed nursing staff to notify EMS the hospital did not have Activase. EMS was notified at the same time they arrived in the ED ambulance bay. -Occurrence was reviewed by Staff F (Manager of Quality/Risk Management) on 06/04/18, 06/25/18, and 06/27/18 each time it was noted "Occurrence Report was viewed", there was no evidence the event was being investigated, causes analyzed, or preventative actions implemented. -Staff U (peer review) reviewed the occurrence on 06/04/18, 06/07/18 at 10:25 am and 1:24 pm, 06/21/18, and 06/28/18, each time it was noted "Occurrence Report was viewed", there was no evidence the event was being investigated, causes analyzed, or preventative actions implemented. -Staff U noted on 06/28/18, Staff S (ED physician on duty on 06/03/18) reported he/she had been made aware of the event and was concerned. It was noted the patient was "in fact in the ED ambulance bay before EMS was alerted there	C 336		

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was no Activase in the hospital" ..."sent to Staff C and Staff F and asked for this to be addressed at the next Medical Executive committee in July". On 09/27/18 at 8:45 am, surveyors requested all Medical Staff and Medical Executive Committee meeting minutes for the past 12 months. There was no evidence provided to surveyors of any Medical Executive Committee meetings after 01/23/18.

-on 07/18/18 at 1:41 pm, Staff U entered in the occurrence "I called and spoke with Staff J (pharmacy) and we do currently have Activase". At 1:42 pm, Staff U noted "Closing Remarks: hospital does have Activase in the building for patient needing Activase". The occurrence was then closed.

-There was no evidence an RCA was initiated to determine why there was no Activase available at the hospital at the time of the patient's arrival, where the two vials of Activase came from the surveyors observed on 09/28/18 or why the patient did not receive initial triage, physician evaluation and prioritization.

-There was no evidence Quality/Risk Management investigated, analyzed the causes through use of the RCA process, identified process issues that could impact patient safety, assisted in implementation of risk reduction strategies, measured and collected data to determine effectiveness of corrective actions to reduce the risk of re-occurrence and communicated lessons learned to a designated Quality Committee, Medical Staff and Medical Executive Committee and the Board of Trustees.

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C 336	Continued From page 27 II. Suicide A review of hospital policy titled "Emergency Medical Screening Examination and Stabilizing Treatment, dated 03/18/18" showed ...A psychiatric emergency was determined when a patient was a danger to him/herself or others ...patients who presented to the ED for a condition addressed through a pre-arranged community plan such as psychiatry an MSE would be performed and treatment initiated prior to transfer of the patient pursuant to the community plan. A review of hospital policy titled "Patient Awaiting Psychiatric Evaluation, dated 12/28/16" showed the patient should evaluated and the need for psychiatric evaluation determined. Review of a hospital document titled "Telemedicine Mental Health Access Agreement, dated 01/14/14" showed a mental health facility would provide licensed mental health professionals to perform telemedicine mental health consultations for patients presenting to the hospital. Review of hospital occurrence report titled "RM Log Incident: intention overdose was discharged w/o psych evaluation or dhs consult" was entered on 09/04/18 by Staff V (ED RN) and showed the following: -Staff U (Peer Review) reviewed the occurrence on 09/06/18 and noted "minor (Patient #5) discharged from ED with suicidal ideation and intentional overdose ...no psychiatric evaluation performed ...DHS not contacted ...14 year old and	C 336		

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suicide attempt, positive drug use not living with parents ...mother states will take to psychiatric hospital for psych consult but no transfer or contact for transfer made. Please comment on reason, transfer not made official from ED prior to discharge."

-On 09/14/18 Staff P (ED RN) noted "I was not aware Tylenol was left in the room ...I do not know the policies and procedures for a minor with an OD (overdose) ...If someone could please orient me to those policies ..."

Review of an untitled hospital document dated 09/06/18 from Staff U showed the occurrence was forwarded to the contracted ED medical group for physician review. Staff U noted a 14 year old patient was "seen in the ED with intentional overdose of Tylenol with suicidal ideation and methamphetamine abuse ...ED physician did not order a psychiatric evaluation ...DHS was not notified of minor suicide attempt and positive drug use ...we feel like the transfer should have been made by the ED physician, in the ED, prior to discharge of the patient."

Review of hospital document titled "QA Study Detail, dated 09/27/18" showed the event was sent to the ED contracted medical group for review. There was no evidence the hospital's peer review committee reviewed and discussed the event to determine process issues or quality of care issues within the ED.

On 10/10/18 at 1:22 pm, Staff F stated quality reviewed the occurrence and determined education was needed. Staff F stated education was provided to nursing staff regarding hospital

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policy for suicide patients. Staff F stated there was not an investigative analysis to determine any process issues and implementation of preventative actions to reduce the risk of re-occurrence for this type of occurrence.

III. Pediatrics

A review of hospital policy, "Scope of Service/Plan of Care: Emergency Department", revision date 01/13/17 showed the patient population served by the ED consisted of newborn, pediatric, adolescent, adult and geriatric patients requiring or seeking medical care. Support services included but were not limited to clinical laboratory studies and x-rays that were to be provided to the patient in a timely manner.

Review of hospital document titled "Occurrence Report Summary, dated 03/22/18" showed Staff W (Pediatrician) sent Patient #7 to the ED for further follow up treatment and "was concerned with ED physician treatment". Staff W sent Patient #7 to ED due to lethargy, fever and stomach pain present for several days. Staff W requested work up by ED physician for possible appendicitis. CT scan and labs were ordered and completed, medication administered and patient was discharged. Staff W called ED to check on patient and was told patient was discharged. Staff W contacted parents and was told patient was taken to another acute care hospital for further treatment.

Review of hospital document titled "QA Study Detail, dated 06/20/18" showed Patient #7's medical chart was referred to ED contracted service for quality review by medical staff. Peer

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review findings showed "advise period of observation instead of discharge from the ED." There was no evidence from review of the incident file the patient's medical record was reviewed by the ED contracted service. There was no evidence the hospital's peer review committee reviewed and discussed the event to determine process issues or quality of care issues within the ED.

Review of Patient #7's incident file showed no evidence the event was being investigated, causes analyzed, or preventative actions implemented by the hospital's QAPI program.

Review of hospital document titled "Occurrence Report Summary, dated 09/09/18" showed one year old infant (Patient # 8) received from ED "in acute respiratory failure, grunting, oxygen saturations 58%...lethargic, trouble breathing, received orders to transfer infant out, before leaving infant intubated."

Review of hospital document titled "QA Study Detail, dated 09/27/18" (identified by Staff F as the medical staff peer review report) showed no evidence of a review of Patient #8's medical care and treatment in the ED. Comments noted "unstable infant not transferred from the ED." There was no evidence the hospital's peer review committee reviewed and discussed the event to determine process issues or quality of care issues within the ED.

Review of hospital document titled "Grievance Process Check List" showed Patient #8's medical record was sent out to the contracted ED service for review on 09/17/18. Review of incident file by surveyors showed no evidence of case review by

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the contracted ED medical provider. There was no evidence the event was being investigated, causes analyzed, or preventative actions implemented by the hospital's quality assurance and improvement program.

A document, "Case Review Form" 05/09/18, showed the form was to be utilized as part of the peer-review process established by the hospital's medical staff bylaws. The conclusion of the review of Patient #10's medical care in the ED showed "there were several findings in the history and physical examination that should have prompted a more thorough evaluation in the emergency department. Treatment did not meet standard of care." The document also showed on 02/08/18, the patient was transferred from a primary care provider's clinic to another facility and underwent surgery for pyloric stenosis.

Review of hospital document titled "Grievance Process Check List" showed Patient #10's medical record was to be reviewed at medical staff peer review on 05/23/18. There was no evidence the hospital's peer review committee reviewed and discussed the event to determine process issues or quality of care issues within the ED. There was no evidence the event was being investigated, causes analyzed, or preventative actions implemented by the hospital's QAPI program.

On 10/10/18 at 1:22 pm, Staff F stated he/she did submit Patient #7's medical record to the contracted medical service for review but does not know why he/she did not have a response from them. Staff F stated "we left this in the contracted medical service's hands". Staff F stated "there should have been a peer review

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completed on Patient #10, I know it went to clinical care and the contracted medical service for review."

IV. Snake Bite

Review of hospital document titled "Grievance Process Check List" showed a complaint was initiated by the quality/peer review personnel due to a concern regarding the care Patient #6 received in the ED. Findings showed the standard of care was not met for the care provided to Patient # 6 for the treatment of the rattlesnake bite. There was no evidence the event was investigated, causes analyzed, or preventative actions implemented by the hospital's QAPI program.

Review of hospital document titled "Continuous Quality Improvement - Patient Complaints and Grievances, dated 04/12/18" showed the outcome of the quality review regarding Patient #6 was an "extremely unexpected" practice that "could have (or did) contribute to patient injury". Medical record was forwarded for medical record by ESS (ED medical staffing group) for peer review.

Review of untitled document (identified as review of Patient #6's medical record by Staff X of the contracted ED service) dated 04/24/18, showed "2 hour observation in the ED for a minimal snakebite with normal vital signs, labs and minimal edema that was not worsening, meets the standard for reasonable care."

On 10/10/18 at 1:22 pm, Staff F stated the ED contracted medical service was responsible for

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peer review of the ED medical staff. Staff F stated he/she or Staff U would send the patient's medical record to the ED contracted service and once completed they would send back a response. Staff F stated the response would get filed and any education or follow-up needed for the ED physicians would be provided by the ED contracted providers. Staff F stated the hospital was responsible for addressing issues with their staff. Staff F stated the hospital did not have a quality committee, it has been combined into the "Super Committee". Staff F stated the "Super Committee" had every hospital department represented and it would be inappropriate to analyze individual patient incidents with them present. Staff F stated there was not a designated committee to discuss individual events in order to analyze causes, identify process issues and determine preventive actions to reduce the risk of re-occurrence. Staff F stated the quality improvement program had not implemented any type of investigative analysis or performance improvement efforts for the events discussed.

On 10/10/18 at 11:59 am, Staff G stated he/she "would have expected the quality and risk manager to have brought these items (events) to my attention, each time the hospital had changed owners then positions had changed ...sometimes I don't know who the quality/risk manager is." Staff G stated issues involving the ED medical staff would be sent to the ED contracted medical service for review and then a representative would come to medical staff peer review to discuss their findings. Staff G stated he/she was not aware of any medical records being reviewed by medical staff peer review.

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C 336	Continued From page 34 On 10/11/18 at 10:30 am, Staff A (COO) stated he/she did not see a conclusion or action on the peer review forms. Staff A stated "It is obvious we are not closing the loop". Staff A stated he/she expected the peer review committee to be reviewing the medical cases to determine if the standard of care was met and if not what actions need to be taken on all cases including those involving the ED and ED physicians. Staff A stated he/she expected the quality program to be reviewing, investigating patient events (occurrences), and analyzing them to determine if hospital processes and procedures were being done.	C 336		
C 342	QUALITY ASSURANCE CFR(s): 485.641(b)(5)(ii) [The program requires that--] the CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program. This STANDARD is not met as evidenced by: Based on record review and interview, the hospital failed to ensure that a functioning QAPI program was implemented and risk reduction strategies formulated to address patient safety issues, medical errors and adverse events identified from occurrences and grievances addressed through the QAPI program. These failed practices resulted in the delayed care for two patients (Patient #6 and 23), worsening health conditions for two patients (Patient #6 and 10), the likelihood for increased	C 342		

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risk of injury to self for one patient (Patient #5), and adverse health outcomes for six patients (Patient #5, 6, 7, 8, 10, and 23), related to the lack of Quality and Risk Management staff's failure to investigate, analyze occurrence reports, identify risk reduction strategies, implement corrective action plans and report findings to a designated Quality Improvement Committee, Medical Staff and Medical Executive Committees and the Board of Trustees.

Findings:

Review of hospital policy titled "Quality Manual (QA/PL Plan), revised 04/01/18) showed the following:

-"The organization must collect data, perform root cause analysis (RCA), preserve data (collect), formulate risk reduction strategies and collect data to demonstrate the effectiveness of the corrective action(s)."

-" ...a faulty process or system invariable permits or compounds the harm, and is the focus of improvement."

Review of hospital document titled "Hospital Super Committee" meeting minutes from 09/06/17 to 06/27/18 showed no evidence of incident reporting for 09/06/17 and reporting of incidents, grievance, or cases sent to peer review for 03/29/18. On 06/27/18 meeting minutes showed the following: incidents (March 18, April 47, May 27), grievances (March 4, April 3, May 3), and cases sent to peer review (March 4, April 7, May 2). There was no evidence cases were

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discussed to include the formulation of risk reduction strategies to address patient safety issues, medical errors and/or adverse events identified from occurrences, grievances and cases sent to peer review.

Review of hospital document titled "Medical Executive Committee" meetings minutes from 04/04/17 to 01/23/18 showed no evidence the quality program reported incidents or grievance data to the medical executive committee. The meeting minutes failed to show evidence patient safety issues, medical errors and adverse events identified from incidents, grievances and cases sent to peer review were discussed to include risk reduction strategies formulated by the medical executive committee.

Review of hospital documents titled "Medical Staff Committee" meeting minutes from 06/13/17 to 01/16/18 showed no evidence the quality program reported incidents or grievance data to the medical staff committee. The meeting minutes failed to show evidence patient safety issues, medical errors and adverse events identified from incidents, grievances and cases sent to peer review were discussed to include risk reduction strategies formulated by the medical staff committee.

Review of hospital documents titled "Board of Trustees (Governing Body)" meeting minutes from 01/24/18 to 08/08/18 showed no evidence the quality program reported incidents or grievance data to the Governing Body. The meeting minutes failed to show evidence patient

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safety issues, medical errors and adverse events identified from incidents, grievances and cases sent to peer review were discussed to include risk reduction strategies and reported to the Governing Body.

Review of hospital documents titled "Special Board of Trustee Committee" meeting minutes from 02/15/17 to 08/08/18 showed no evidence the quality program reported incidents or grievance data to the Governing Body. The meeting minutes failed to show evidence patient safety issues, medical errors and adverse events identified from incidents, grievances and cases sent to peer review were discussed to include risk reduction strategies and reported to the Governing Body.

On 10/10/18 at 1:22 pm, Staff F stated, he/she was responsible for evaluating all patient care services from a quality standpoint. Staff F stated, he/she was not responsible for taking quality data including incidents and grievances to medical staff and Governing Body. Staff F stated, the quality improvement program had not implemented any type of investigative analysis or performance improvement efforts for the events discussed.

On 10/10/18 at 2:30 pm, Staff C stated, he/she was responsible for taking quality indicator data to medical staff committee and the Governing Body. Staff C stated, medical staff and Governing Body did not discuss individual incidents and grievances.

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C 343	QUALITY ASSURANCE CFR(s): 485.641(b)(5)(iii) [The program requires that--] the CAH documents the outcome of all remedial action. This STANDARD is not met as evidenced by: Based on record review and interviews, the hospital failed to ensure a functioning QAPI program was implemented so that data was collected to demonstrate the effectiveness of corrective action(s) from risk reduction strategies for medical errors, patient safety and adverse events. These failed practices resulted in the delayed care for two patients (Patient #6 and 23) , worsening health conditions for two patients (Patient #6 and 10), the likelihood for increased risk of injury to self for one patient (Patient #5), and adverse health outcomes for six patients (Patient #5, 6, 7, 8, 10, and 23), related to the lack of Quality and Risk Management staff's failure to investigate, analyze occurrence reports, identify risk reduction strategies, implement corrective action plans and report findings to a designated Quality Improvement Committee, Medical Staff and Medical Executive Committees and the Board of Trustees. Findings: Review of hospital policy titled "Quality Manual (QA/PL Plan), revised 04/01/18) showed the following:	C 343		

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C 343	Continued From page 39 - "The organization must collect data ...to demonstrate the effectiveness of the corrective action(s)." Review of hospital document titled "Hospital Super Committee" meeting minutes from 09/06/17 to 06/27/18 showed no evidence the quality program was analyzing patient safety, medical errors and adverse patient events, determining preventative action plans, and collecting data to determine the effectiveness of the preventative action plans to ensure sustainability and decreased risk of re-occurrence. Review of hospital document titled "Medical Executive Committee" meetings minutes from 04/04/17 to 01/23/18 failed to show evidence the quality program presented to the medical executive committee patient safety, medical errors and adverse events identified from incidents, grievances, and cases sent to peer review were analyzed, preventative action plans determined and data reported and trended to determine the effectiveness of the preventative action plans to ensure sustainability and decreased risk of re-occurrence. Review of hospital documents titled "Medical Staff Committee" meeting minutes from 06/13/17 to 01/16/18 showed no evidence the quality program presented to the medical staff committee, patient safety, medical errors and adverse events identified from incidents, grievances, and cases sent to peer review were analyzed, preventative action plans determined and data reported and	C 343		

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C 343	Continued From page 40 trended to determine the effectiveness of the preventative action plans to ensure sustainability and decreased risk of re-occurrence. Review of hospital documents titled "Board of Trustees (Governing Body)" meeting minutes from 01/24/18 to 08/08/18 showed no evidence the quality program presented to the Governing Body, patient safety, medical errors and adverse events identified from incidents, grievances, and cases sent to peer review were analyzed, preventative action plans determined and data reported and trended to determine the effectiveness of the preventative action plans to ensure sustainability and decreased risk of re-occurrence. Review of hospital documents titled "Special Board of Trustee Committee" meeting minutes from 02/15/17 to 08/08/18 showed no evidence the quality program presented to the Governing Body, patient safety, medical errors and adverse events identified from incidents, grievances and cases sent to peer review were analyzed, preventative action plans determined and data reported and trended to determine the effectiveness of the preventative action plans to ensure sustainability and decreased risk of re-occurrence. On 10/10/18 at 1:22 pm, Staff F stated, he/she was responsible for evaluating all patient care services from a quality standpoint. Staff F stated he/she was not responsible for taking quality data including incidents and grievances to medical staff and Governing Body. Staff F stated the	C 343		

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C 343	Continued From page 41 quality improvement program had not implemented any type of investigative analysis or performance improvement efforts for the events discussed. On 10/10/18 at 2:30 pm, Staff C stated he/she was responsible for taking quality indicator data to medical staff committee and the Governing Body. Staff C stated medical staff and Governing Body did not discuss individual incidents and grievances.	C 343		