

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

PRINTED: 11/08/2019  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>450289</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>09/27/2019</b>
NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 000	<p>INITIAL COMMENTS</p> <p>Note: The CMS-2567 is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. If information is inadvertently changed by the provider, you should notify the state Survey Agency. If the SA notices any discrepancy in the information related to scope and severity assigned or the deficiency citation(s), the SA will report this occurrence to the Dallas Regional Office. The Regional Office will make a referral of possible fraud to the Office of the Inspector General (OIG).</p> <p>*****</p> <p>A survey was made to the above facility on 09/16/2019 - 09/27/2019 to conduct a follow up survey, a Medicare Recertification survey, and survey of multiple complaints. The survey team entered Hospital's campus 1 and 2 of the system on 09/16/2019. An entrance conference was held with the Facility's Executive staff and Administrative staff.</p> <p>A copy of instructions on writing acceptable plans of corrections for potential deficiencies was provided to the administrative representatives along with other required documents for the survey. The purpose and methodology of the survey was explained to administrative representatives. Opportunities were provided for questions, answers and discussion.</p> <p>An exit conference was held on 09/27/2019. Findings of the survey were discussed with</p>	A 000			

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

TITLE

(X6) DATE

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	<p>Continued From page 1</p> <p>administrative representatives. Deficiencies were cited at standard and condition level. Opportunities were provided for questions, answers, and discussion. Opportunity was also provided for the facility to provide evidence where non-compliance was determined, none was provided. The facility was not in compliance with 42 CFR (Code of Federal Regulation) part 482 as surveyed this date.</p> <p>Conditions not met included: 482.12: Governing Body 482.13: Patient Right 482.21: QAPI 482.23: Nursing Service 482.27: Laboratory Services 482.43: Infection Control 482.51: Surgical Services 482.12: Rehabilitation Service</p> <p>Immediate Jeopardy to the health and safety of patients (IJ) were identified under the Medicare Conditions of Participation of Surgical Services, Patient Rights, Infection Control, and Governing Body. The facility's administrative staff were notified of the IJ on the following dates: 09/18/2019, 9/20/2019, 09/23/2019, and 09/25/2019.</p> <p>Immediate Jeopardy Patient Rights - Hemodialysis:</p> <p>The facility's direct care staff failed to follow the manufacturer's direction for use when testing water used for hemodialysis of patients for total chlorine in 1 of 1 observation. Failure to test</p>	A 000			

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A 000	<p>Continued From page 2</p> <p>water using the correct volume of water recommended by the manufacturer for the water treatment system has the potential of giving an incorrect result as to the presence of chlorine in the water which has the likelihood to harm all patients receiving hemodialysis treatment in the facility.</p> <p>Systems were implemented by the facility on 09/26/2019 and 09/27/2019, and acceptable plans of corrections were provided to the survey team by the facility to remove the IJ identified at the hospital system.</p> <p>Remediation Plan to remove the IJ for Hemodialysis included:</p> <p>Development and implementation of training module for Water Quality.</p> <p>Training of all staff at Hospital (1 and 2)</p> <p>Development and implementation of skills assessment for all staff associated with hemodialysis</p> <p>Development and implementation of competency training test and water skills</p> <p>Mandatory nursing education and competency for all staff working in dialysis.</p> <p>IJ was found under Surgical Services:</p> <p>On September 23, 2019, at hospital (1), it was determined that the facility failed to ensure the temperature in the Operating room (OR) was</p>	A 000			

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A 000	<p>Continued From page 3</p> <p>within acceptable standards to inhibit microbial growth, reduce the risk of infection, promote patient comfort, and assure the physical safety of all patients. The temperature and humidity was out of range for 33 of 33 days reviewed from August 18, 2019, to September 19, 2019. The facility engineering department was not accurately monitoring the temperature and humidity in the Operating Rooms and making notification to the operating room staff when levels were out of range. There was no documentation on the log to indicate corrective action was taken and the temperature on follow up after corrective action was done. The operating room staff was not knowledgeable of the temperature requirements prior to opening sterile cases in the Operating Room. There was no monitoring of temperature and humidity in the Cath Lab #1, Cath Lab #2, and Cath lab storage room where sterile wrapped pacemaker trays were stored.</p> <p>On September 26, 2019, the Administrative Staff provided an acceptable plan of removal to abate the Immediate Jeopardy. The plan was as follows:</p> <p>"--- Health System: Remediation Plan for Monitoring Temperature and Humidity</p> <p>Findings:</p> <ul style="list-style-type: none"> <li>- Failure to maintain temperature and humidity in operating rooms within appropriate ranges</li> <li>- Failure to maintain temperature and humidity in cardiac catheterization lab within appropriate ranges</li> </ul>	A 000			

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A 000	<p>Continued From page 4</p> <ul style="list-style-type: none"> <li>- Lack of evidence of continuous monitoring of temperature and humidity in operating rooms and cardiac catheterization lab</li> <li>- Lack of staff knowledge of temperature requirements, monitoring method and appropriate escalation and remediation of temperature and humidity fallouts</li> <li>- Failure to continuously monitor temperature and humidity within storage areas for sterile Instrumentation</li> </ul> <p>High Level Remediation</p> <p>Temperature and Humidity Monitoring Plan</p> <p>Operating Rooms, Sterile Core, Sterile Processing Department: Health System has a continuous monitoring system for operating rooms, sterile core ,and the sterile processing department which is monitored by the Facilities Department at hospital 1 and 2. Health System will engage Johnson Controls to install monitoring displays to enable real-time visibility of temperature and humidity by all staff. These will be installed in all operating, central core, and sterile processing department areas.</p> <p>Cardiac Catheterization</p> <p>Health System identified that the cardiac catheterization lab at Hospital (1) was not currently equipped for continuous monitoring. Johnson Control has been contacted to provide an assessment and proposal on the installation of</p>	A 000		

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A 000	<p>Continued From page 5</p> <p>continuous monitoring capabilities of the cardiac catheterization lab at Hospital (1) and installation of monitoring displays to facilitate staff visibility of temperature and humidity. In the interim, Harris Health has developed a process to maintain visibility of temperature and humidity in the cardiac catheterization lab. Temperature and humidity monitors will be installed in the cardiac catheterization lab at Hospital (1) by September 27, 2019, and staff will be required to check and log the temperature and humidity prior to every case.</p> <p>Health System will create a log sheet template to monitor the temperature and humidity in the cardiac catheterization lab at Hospital (1). The log sheet will include the following: the normal parameters for temperature and humidity, actions taken, and the name and signature of the staff member who reviewed the temperature and humidity monitor readings. The log will be implemented by September 27, 2019.</p> <p>Development of System Policy:</p> <p>Health System drafted and will adopt, effective September 26, 2019, a system policy, "Maintaining Appropriate Temperature and Relative Humidity Ranges in Operative, Procedural, and Storage Areas for Sterile Instrumentation," that addresses the following: Temperature and Humidity Parameters.</p> <p>The temperature and humidity parameters required in operating rooms and other procedure rooms including, but not limited to the cardiac catheterization labs.</p>	A 000			

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A 000	<p>Continued From page 6</p> <p>Continuous Monitoring of Operating Rooms, Procedure Rooms. Requirement to continuously monitor temperature and humidity in operating rooms and procedure rooms, including but not limited to the cardiac catheterization labs.</p> <p>Requirement for engineering to validate and document that temperature and humidity are in range in advance of the first scheduled case of the day. Continuous Monitoring of Storage Areas for Sterile Instrumentation. Requirement to continuously monitor temperature and humidity in sterile processing department.</p> <p>Escalation and Remediation of Temperature and Humidity Fallouts</p> <p>The requirement that engineering escalate fallouts of either temperature or humidity in the operating rooms and in the procedure rooms, specifically, the cardiac catheterization labs, to the relevant department. The requirement that engineering escalate fallouts of either temperature or humidity in storage areas for sterile instrumentation to Health's Sterile Processing Department for assessment of risk and appropriate remediation.</p> <p>The requirement that engineering recheck that temperature and humidity are back in the appropriate range following remediation. The requirement that engineering ensure that all remediation and validation is documented. Until such time that continuous monitoring is installed in the cardiac catheterization lab, assigned departmental staff will be responsible for checking the temperature and humidity and</p>	A 000			

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A 000	<p>Continued From page 7 escalating to Facilities when out of range.</p> <p>Deviations in Temperature and Humidity</p> <p>The process that must be followed when the clinical conditions of a Patient warrant a deviation in the defined temperature requirements The process that must be followed to return the room to the defined temperature immediately after the resolution of the clinical condition of a patient requiring a deviation in the defined temperature requirement.</p> <p>Education of Staff:</p> <p>Applicable Health System nursing staff and clinical support staff assigned to its operative and cardiac catheterization lab and storage areas for sterile implementation and facilities engineering staff will be educated on Health Policy "Maintaining Appropriate Temperature and Relative Humidity Ranges in Operative, Procedural and Storage Areas for Sterile Instrumentation" policy beginning on September 26, 2019, with an estimated completion date of October 2, 2019.</p> <p>The education provided to staff will cover the following topics:</p> <p>Appropriate temperature and humidity ranges in operating and procedure rooms and storage areas for sterile instrumentation rooms. Continuous monitoring requirements for the operating rooms, procedure rooms, and storage areas for sterile instrumentation. Escalation and remediation process for a addressing</p>	A 000			



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A 000	<p>Continued From page 8</p> <p>temperature and humidity fallouts. Documentation of the scheduled monitoring of temperature and humidity specific to the interim monitoring plan for the cardiac catheterization labs.</p> <p>Monitoring Plan</p> <p>Compliance with Harris Health's newly drafted "Maintaining Appropriate Temperature and Relative Humidity Ranges in Operative, Procedural, and Storage Areas for Sterile Instrumentation" Policy will be monitored as follows:</p> <p>Operating Rooms and Storage Areas for Sterile Implementation:</p> <p>To ensure compliance with Harris Health's Policy "Maintaining Appropriate Temperature and Relative Humidity Ranges in Operative, Procedural, and Storage Areas for Sterile Instrumentation" requirement that the temperature and humidity be continuously monitored. Health's Infection Prevention Department will implement a monitoring plan beginning on September 27, 2019, that will include auditing the temperature and humidity and any deviations in the operating rooms and cardiac catheterization labs.</p> <p>The audit will assess the compliance with completion of the temperature and humidity monitoring logs in the cardiac catheterization lab. This assessment will occur weekly for at least eight weeks and/or until 100% compliance is achieved. Thereafter, Health's Infection Prevention Department will audit until remains</p>	A 000			

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A 000	<p>Continued From page 9</p> <p>within the prescribed parameters for four consecutive months and/or until 100% compliance is achieved. Subsequent to achieving compliance, the Infection Prevention Department will transition their audit to a quarterly review. All identified fallouts will be reported to the pavilion Quality Review Committee, to the system-level Quality Governance Council, and to the Board of Trustees.</p> <p>The audit will assess the temperature and humidity in these areas to confirm that both the temperature and humidity remained within the required parameters. This assessment will occur weekly for at least eight weeks and/or until 100% compliance is achieved. Thereafter, Health's Infection Prevention Department will audit whether the temperature and humidity in the above areas remains within the prescribed parameters for four consecutive months and/or until 100% compliance is achieved. Subsequent to achieving compliance, the Infection Prevention Department will transition their audit to a quarterly review. All identified fallouts will be reported to the pavilion Quality Review Committee, to the system-level Quality Governance Council, and to the Board of Trustees."</p> <p>IJ was found at 482.51 Surgical Services</p> <p>On September 18, 2019, it was determined the facility failed to ensure the Transesophageal Echocardiogram Endoscope (TEE) and the transvaginal probes were stored in a manner that would protect them from damage or contamination and that it was consistent with national guidelines and manufacturers'</p>	A 000			

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A 000	<p>Continued From page 10</p> <p>recommendations such as hanging vertically in a cabinet and storing in a clean environment. Also, the facility failed to monitor the temperature and humidity of the storage areas where the Transesophageal Echocardiogram Endoscope (TEE) and the transvaginal probes were stored.</p> <p>On September 26, 2019, the Administrative Staff provided an acceptable plan of removal for the Immediate Jeopardy. The plan was as follows:</p> <p>"--- Health System: Remediation Plan for Scopes and Probes:</p> <p>Findings:</p> <ul style="list-style-type: none"> <li>- Failure to properly store Transesophageal Echocardiogram ("TEE") probes.</li> <li>- Failure to properly store process and disinfect Transvaginal ultrasound probes.</li> <li>- Lack of a guideline addressing the timeframe that TEE probes and transvaginal probes are considered clean after processing and disinfection while in storage.</li> <li>- Failure to properly monitor temperature and humidity in storage areas containing probes.</li> </ul> <p>High Level Remediation Plan:</p> <p>Transesophageal Echocardiogram ("TEE") Probes</p> <p>Storage</p>	A 000			

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A 000	<p>Continued From page 11</p> <ul style="list-style-type: none"> <li>- As per (revised) Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices and the new draft guideline, Health 1303.03 "Transesophageal Echocardiogram (TEE) Probe Guidelines for Cleaning and Disinfection."</li> </ul> <p>Health System has purchased and installed the following storage cabinets for TEE probe storage:</p> <ul style="list-style-type: none"> <li>- Two (2) TEE Probe storage cabinets in the cardiology suite and one (1) storage cabinet in the operating suite have been installed for TEE probe storage at ( hospital 1),</li> <li>- One (1) storage cabinet in the cardiology suite has been installed for TEE probe storage at Hospital (2).</li> <li>- These cabinets were installed and functional with the TEE probes in place on September 23, 2019, at Hospital (1) and September 22, 2019, at Hospital (2).</li> <li>- All TEE probes are now stored vertically in cabinets with a HEPA filter in a room that has temperature and humidity monitoring.</li> <li>- A concurrent evaluation is being conducted to identify and remediate areas that require continuous monitoring of temperature and humidity. These remediation activities will be addressed in our corrective action plan on temperature and humidity monitoring in appropriate areas.</li> </ul> <p>Reprocessing and Disinfection of the TEE Probe</p>	A 000			

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A 000	<p>Continued From page 12</p> <ul style="list-style-type: none"> <li>- Health System has written a new guideline, Health 1303.03 "Transesophageal Echocardiogram Probe Guidelines for Cleaning and Disinfection" that was approved on Tuesday, September 24, 2019. This guideline defines the procedure for pre-cleaning, cleaning, and high-level disinfection of the TEE Probes according to the manufacturers' recommendations.</li> <li>- As per new guideline, TEE probe has not been utilized by the 14th day after it was reprocessed and disinfected, the TEE probe will be reprocessed and disinfected again.</li> </ul> <p>Transvaginal Ultrasound Probes</p> <p>Storage:</p> <ul style="list-style-type: none"> <li>- Health System conducted a gap analysis on September 22 and 23, 2019, and identified where cabinets are needed for storage of transvaginal probes. A total of ten ultrasound probe storage cabinets were ordered for the storage of transvaginal probes on September 25, 2019.</li> <li>The vendor has confirmed shipment of cabinets by October 4, 2019.</li> <li>- At Hospital (1), four ultrasound probe storage cabinets were ordered for the storage of transvaginal probes. Two cabinets were ordered for Radiology, one cabinet for Labor &amp; Delivery, and one for the Obstetric Clinic.</li> <li>- At ( Hospital (2), In Labor &amp; Delivery, one (1) ultrasound probe storage cabinet has already</li> </ul>	A 000			

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A 000	<p>Continued From page 13</p> <p>been received and installed for the storage of transvaginal probes. Six (6) ultrasound probe storage cabinets were ordered for the storage of transvaginal probes. Three cabinets (3) were ordered for the Obstetric Clinic and three cabinets (3) were ordered for Radiology. In Labor &amp; Delivery, one (1) ultrasound probe storage cabinet has already been received and installed for the storage of transvaginal probes.</p> <p>- As per (revised) Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices, the cabinets will be immediately installed in areas with transvaginal probes upon arrival and once biomedical checks of the cabinets are completed. Transfer of transvaginal probes to cabinets will be done after reprocessing probes.</p> <p>- Until such time as the cabinets are received, Health is ensuring that all transvaginal ultrasound probes are stored with a clean sheath in a rack or shelf in a clean area in a flat, uncoiled position.</p> <p>Reprocessing and Disinfection of the Transvaginal Probe</p> <p>- As per (revised) Harris Health Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices, when a transvaginal probe has not been utilized by the 14th day after it was reprocessed and disinfected, the transvaginal probe will be reprocessed and disinfected again.</p> <p>Policy Revisions</p>	A 000		

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A 000	<p>Continued From page 14</p> <p>--- Health System has written a guideline, Health 1303.03 "Transesophageal Echocardiogram (TEE) Scope Guidelines for Cleaning and Disinfection"</p> <p>- Approved on Tuesday, September 24, 2019.</p> <p>- Revisions include: defining the procedure for pre-cleaning, cleaning, and high-level disinfection of the TEE Probes according to the manufacturers' recommendations.</p> <p>- Additionally, the guideline states when a TEE probe has not been utilized, on the 14th day after it was initially processed and disinfected, the TEE probe will be reprocessed and disinfected.</p> <p>--- Health Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices</p> <p>- Revised and approved on September 24, 2019.</p> <p>- Revisions include: defining storage and transportation of transvaginal probes, requirement for vertical storage of the probes and endoscopes, per manufacturers' guidelines, and temperature and humidity monitoring.</p> <p>Additionally, the policy states when a transvaginal probe has not been utilized, on the 14th day after it was initially processed and disinfected, the transvaginal probe will be reprocessed and disinfected.</p> <p>Staff Education</p> <p>---- Health's nursing staff, technicians and central</p>	A 000			

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A 000	<p>Continued From page 15</p> <p>sterilization processing staff began to receive education on September 23, 2019, with a completion date of September 25, 2019. The staff education items include:</p> <ul style="list-style-type: none"> <li>- The proper storage, cleaning, and sterilization of Transvaginal Probes as set forth in the revisions to Health Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices, and in accordance with manufacturers' recommendations.</li> <li>- The storage, cleaning, and sterilization requirements for TEE probes specified in Health 1303.03 Transesophageal Echocardiogram Scope Guidelines for Cleaning and Disinfection, and in accordance with manufacturers' recommendations. This includes reprocessing and disinfection on the 14th day after the prior processing and disinfection.</li> <li>- Responsibilities outlined in Health Policy 1303, Pre-Cleaning, Sterilization, High- and Low-Level Disinfection, and Storage of Processed Patient Care Devices regarding the daily assessment and continuous monitoring of the temperature and humidity in rooms containing probes and the requirement that fallouts are immediately escalated for remediation.</li> <li>- Further education related to appropriate storage of probes without sheaths, that shelf life is determined by manufacturer ' s guidelines, and that humidity for storage of sterile items will not exceed sixty percent (60%), in accordance with Health Policy 1303, will be completed for applicable staff by October 2, 2019.</li> </ul>	A 000			



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A 000	Continued From page 16  Monitoring Plan  · Compliance with Harris Health Policy 1303, Pre-Cleaning, Sterilization, High- and Low-Level Disinfection, and Storage of Processed Patient Care Devices will be monitored as follows:  - Storage Requirements: To monitor and ensure compliance with the revisions to and requirements set forth in Health Policy 1303, Pre-Cleaning, Sterilization, High and Low Level Disinfection and Storage of Processed Patient Care Devices, Harris Health's Quality and Infection Prevention departments will perform a weekly audit of the storage of TEE Probes, and Transvaginal Probes beginning on September 27, 2019. Specifically, these departments will monitor the storage weekly for eight (8) weeks and/or until one hundred percent (100%) compliance is achieved. Thereafter, monthly reviews will be conducted for four (4) consecutive months and one hundred percent (100%) compliance is continuously demonstrated. Any identified deficiencies will be immediately escalated to the Director of the unit and remediated. All fallouts will be reported to the Pavilion Quality Review Committees and if necessary, to the system-level Quality Governance Council.  Temperature and Humidity Monitoring  To assess compliance with Health Policy 1303's temperature and humidity assessment, monitoring, and escalation requirements for storage rooms containing TEE and Transvaginal Probes, Health's Infection Prevention and Quality departments will implement a monitoring plan	A 000			

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A 000	<p>Continued From page 17</p> <p>beginning on September 27, 2019. Specifically, these departments will monitor the temperature and humidity logs weekly for eight (8) weeks and/or until one hundred percent (100%) compliance is achieved. Thereafter, monthly reviews will be conducted for four (4) consecutive months and one hundred percent (100%) compliance is continuously demonstrated. After meeting this requirement, the Quality and Infection Prevention departments will move to quarterly reviews. All fallouts will be reported to Pavilion Quality Review Committees and if necessary, to the system-level Quality Governance Council.</p> <p>Compliance with Health Transesophageal Echocardiogram (TEE) Scope Guidelines for Cleaning and Disinfection</p> <p>To measure the effectiveness of and compliance with the cleaning requirements set forth in the newly developed and adopted Transesophageal Echocardiogram (TEE) Scope Guidelines for Cleaning and Disinfection, Health will implement a monitoring plan. Specifically, Health's Infection Prevention and Quality departments will conduct a weekly audit to assess compliance with the 14-day requirement for reprocessing and disinfection if a TEE or Transvaginal probes is not utilized for eight (8) weeks beginning on September 27, 2019. After a period of eight (8) weeks and once one hundred percent (100%) compliance is achieved, the monitoring plan will be adjusted to a monthly review for four (4) consecutive months until compliance is evidence. Thereafter, there will be quarterly reviews. All fallouts will be reported to the Pavilion Quality Review Committees and if necessary, to the</p>	A 000			

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A 000	<p>Continued From page 18 system level Quality Governance Council."</p> <p>IJ was found under Governing Body ( Maternal Health)</p> <p>On September 19, 2019, at 9:30 am, the hospital leadership met with the survey team to discuss a maternal death that occurred on September 12, 2019, at Hospital 2. During the meeting, leadership presented the case with the preliminary Root Cause Analysis (RCA). The survey team indicated that the case was going to be reviewed.</p> <p>Based on record reviews, interviews, and observation, an Immediate Jeopardy situation was called on Monday, September 25, 2019, at 10:30 am. The hospital Medical Staff, Anesthesia, and Nursing failed to effectively communicate amongst themselves concerning a critical medical situation with one obstetric patient. The failure of the medical team to identify this critical event while administering care to this patient led to a negative outcome for Patient #429. This failed practice has the potential to affect obstetric patients receiving prenatal care, including labor and delivery in Hospital 2.</p> <p>IJ was found under 482.42 Infection Control</p> <p>On September 20, 2019, at hospital (1 and 2) it was determined the facility:</p> <p>A. Failed to ensure patient equipment used in isolation rooms and contaminated areas were identified and labeled assuring appropriate cleaning methods and proper disinfectants were</p>	A 000		

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A 000	<p>Continued From page 19</p> <p>performed to all soiled and contaminated patient equipment preventing the spread of infectious disease to patients and staff.</p> <p>B. Failed to ensure patient equipment in the Decontamination Room, Warehouse, and Telemonitor rooms were properly labeled, transported, inspected, and stored in a safe manner.</p> <p>C. Failed to ensure sterile and clean patient supplies were stored in a clean area protected from extreme temperature and humidity, and that sterile supplies and instruments were stored according to professional standards to prevent contamination and microbial growth.</p> <p>D. Failed to ensure the Infection Control Preventionist (ICP) monitored the warehouse, telemonitor room, and shared rooms to assure:</p> <ul style="list-style-type: none"> <li>- a clean and sanitary environment was established</li> <li>- appropriate use of disinfectant and PPE were available, and that training was provided</li> <li>- oversight to the Central Supply Technicians, Environmental Services for proper cleaning, sanitation and storage of patient equipment and supplies</li> </ul> <p>On September 27, 2019, the Administrative Staff provided an acceptable plan of removal to abate the Immediate Jeopardy. The plan was as follows:</p> <p>The document "_____Health System:</p>	A 000			

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A 000	<p>Continued From page 20</p> <p>Remediation Plan for Supply Chain at Hospital # 2" stated in part,</p> <p>"... Findings:</p> <ul style="list-style-type: none"> <li>- No humidity or temperature control monitoring of sterile supplies</li> <li>- No separation of sterile and non-sterile supplies</li> <li>- Unclean conditions of several spaces: Warehouse, Dirty Equipment Room, Supply Room, Central Supply</li> <li>- Concerns regarding environment including no access to hot water in dirty equipment room</li> <li>- Staff inability to articulate processes</li> <li>- Lack of appropriate PPE (Personal Protective Equipment) worn by staff and inability to articulate policy or training received</li> <li>- Lack of process to identify equipment used by patients with C. Diff</li> <li>- Corrugated cardboard co-mingled with sterile supplies</li> <li>- Insufficient involvement of Infection Prevention (IP)</li> </ul> <p>High Level Remediation Plan</p> <p>Central Supplies</p> <p>- In consultation with our IP manager, we have identified and created separate room for both</p>	A 000		

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A 000	<p>Continued From page 21</p> <p>"clean equipment" and "dirty equipment".</p> <ul style="list-style-type: none"> <li>- We have relocated the dirty equipment room. A temporary HEPA filter is in place. An exhaust engineer was on-site Monday, September 23, 2019, to evaluate installation of a permanent exhaust system.</li> <li>- PPE is available at the entry to the Dirty Equipment Room and staff has been educated by IP staff on proper use.</li> <li>- Central Supply Staff have also been educated by IP staff on how to identify and clean equipment used for C. diff patients.</li> <li>- Nursing staff have been re-educated on the requirement to cover equipment used for C. diff patients with black bags before transporting for cleaning.</li> <li>- We have relocated clean equipment to a new Clean Equipment room.</li> <li>- Temperature and relative humidity in Clean Room will be maintained.</li> <li>- All Central Supply Staff have been re-educated and re-oriented by IP staff on all processes and infection prevention.</li> <li>- Weekly monitoring will be conducted by IP for compliance with appropriate practice and process.</li> </ul> <p>Sterile Supplies</p> <ul style="list-style-type: none"> <li>- In consultation with our IP manager, we</li> </ul>	A 000			

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A 000	<p>Continued From page 22</p> <p>identified an appropriate temporary location for the storage of sterile supplies.</p> <ul style="list-style-type: none"> <li>- Sterile supplies have been relocated to the temporary location in a containment area in a badged security access room.</li> <li>- IP advised on appropriate temperature and humidity requirements. EFI air quality verification completed.</li> <li>- Temperature and relative humidity in Clean Room will be maintained.</li> <li>- IP will monitor proper practice and process on a weekly basis.</li> <li>- All sterile and non-sterile supplies have been moved to separate racks.</li> <li>- All liquids have been moved to the bottom shelf.</li> <li>- Posted signage to direct staff that only clean beds, properly covered with plastic, are to be stored in the badged security access room that contain the sterile supply containment area.</li> <li>- Warehouse area have been reorganized and cleaned and processes redesigned.</li> <li>- At the direction of our IP manager, old, expired, and compromised supplies have been discarded.</li> <li>- When possible, broken or unused equipment has been removed or discarded.</li> <li>- The warehouse has been reorganized to maintain separation of "clean" and "dirty".</li> </ul>	A 000			

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A 000	<p>Continued From page 23</p> <ul style="list-style-type: none"> <li>- Much of the contents of the warehouse have been moved, delivered, discarded and/or put into service.</li> <li>- Corrugated cardboard has been greatly reduced.</li> <li>- The system has developed a process to ensure laboratory supplies are delivered to end users within the appropriate time period and under appropriate temperature control.</li> <li>- All Warehouse Staff have been re-educated and re-oriented by IP staff on topic including infection prevention.</li> <li>- In an effort to better control the temperature humidity in the warehouse, we are keeping doors closed when shipments are not being received.</li> <li>- Weekly monitoring will be performed by IP staff to ensure compliance with practice and process for storage, humidity and temperature controls..."</li> </ul> <p>Glossary</p> <p>Acyclovir: One of a group of antiviral drugs that acts against the herpes viruses, including: Herpes simplex 1, which causes cold sores. Herpes simplex 2, which causes genital herpes. Varicella-zoster, which causes both chickenpox and shingles.</p> <p>Amoxicillin: is an antibiotic often used for the treatment of a number of bacterial infections. These include middle ear infection, strep throat, pneumonia, skin infections, and urinary tract</p>	A 000			



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A 000	Continued From page 24 infections among others  Amniotic sac, commonly called the bag of waters, sometimes the membranes, is the sac in which the fetus develops in amniotes (womb) .  Bougie: A slender, flexible, cylindrical instrument that is inserted into a bodily canal, such as the urethra, to dilate, examine, or medicate.  Bronchoscopy: is a procedure in which a hollow, flexible tube is inserted into the airways, allowing the physician to visually examine the lower airways, including the larynx, trachea, bronchi, and bronchioles  Caesarean section: also known as C-section, or caesarean delivery, is the use of surgery to deliver babies.  Carboprost: induces contractions and can trigger abortion in early pregnancy. It also reduces postpartum bleeding.  Cardiomyopathy: An acquired or inherited disease of the heart muscle which makes it difficult for the heart to pump blood to other parts of the body.  C Diff: Clostridium Difficile (C. diff.) is a type of bacteria that lives in many people's intestines. C. diff. is part of the normal balance of bacteria in your body. It also lives in the environment, such as in soil, water, and animal feces.  Chorioamnionitis: also known as intra-amniotic infection is an inflammation of the fetal membranes due to a bacterial infection.	A 000			

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A 000	<p>Continued From page 25</p> <p>Defibrillation: the stopping of fibrillation of the heart by administering a controlled electric shock in order to allow restoration of the normal rhythm.</p> <p>Dialysate: Dialysate is a solution used in renal dialysis which is needed when normal kidney function fails.</p> <p>DIC: Disseminated intravascular coagulation (DIC) is a condition that prevents your body from controlling blood clotting and bleeding. Initially, blood clots form in many areas of your body. Your body responds by overproducing an agent to break down the blood clots. This leads to excessive bleeding, which can be life-threatening.</p> <p>D- Dimer: It is a quick, non-invasive test to help rule out abnormal or excess clotting as the underlying cause.</p> <p>DKA: Diabetic ketoacidosis (DKA) is a serious condition that can occur in diabetes. DKA happens when acidic substances, called ketones, build up in your body. Ketones are formed when your body burns fat for fuel instead of sugar, or glucose. That can happen if you don't have enough insulin in your body to help you process sugars.</p> <p>EKG: a graphical recording of the cardiac cycle produced by an electrocardiograph cardiogram, ECG, electrocardiogram.</p> <p>EMTALA (Emergency Medical Treatment and Labor Act): The Emergency Medical Treatment and Active Labor Act is an act of the United States Congress, passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act. It requires hospital Emergency Departments that</p>	A 000			

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A 000	<p>Continued From page 26</p> <p>accept payments from Medicare to provide an appropriate medical screening examination to anyone seeking treatment for a medical condition, regardless of citizenship, legal status, or ability to pay</p> <p>ESRD: End-Stage Renal Disease (ESRD) is a medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. Beneficiaries may become entitled to Medicare based on ESRD.</p> <p>Hemabate is a form of prostaglandin (a hormone-like substance that occurs naturally in the body). Prostaglandins help to control functions in the body such as blood pressure and muscle contractions. Hemabate is used to treat severe bleeding after childbirth (postpartum</p> <p>Hemodialysis: hemodialysis is a method that is used to remove waste products such as creatinine and urea and free water from the blood when the kidneys are in a state of renal failure.</p> <p>Magill forceps forceps used to introduce an endotracheal tube into the trachea during nasotracheal intubation. obstetric forceps forceps for extracting the fetal head from the maternal passages.</p> <p>Material Safety Data Sheet (MSDS): is a document that contains information on the potential health effects of exposure to chemicals, or other potentially dangerous substances, and on safe working procedures when handling chemical products. It is an essential starting point for the development of a complete health and</p>	A 000			

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A 000	<p>Continued From page 27 safety program</p> <p>Magnesium sulfate. Magnesium sulfate: A remarkably versatile compound administered intramuscularly and intravenously as an anticonvulsant and as a tocolytic agent (to halt premature labor), taken by mouth as a fast-acting laxative, and applied locally as an anti-inflammatory.</p> <p>MAP: The Mean Arterial Pressure refers to the average pressure of the blood circulating through a person's arteries, during the cardiac cycle. The value of the mean arterial pressure is normally derived from the systolic blood pressure and diastolic blood pressure of the patient</p> <p>Obstetrics: is the field of study concentrated on pregnancy, childbirth, and the postpartum period.</p> <p>A paramedic: is a specialist healthcare professional who responds to emergency calls for medical help outside of a hospital.</p> <p>Peel Packs: peel packs are developed for packing individual instruments, smaller sets and other items</p> <p>Phlebotomy: is the process of making a puncture in a vein with a needle, for the purpose of taking blood.</p> <p>Pitocin: is a hormone that is used to induce labor or strengthen uterine contractions, or to control bleeding after childbirth.</p> <p>Potts Scissors: a fine-toothed, multiple-point, vascular fixation clamp that imparts limited trauma to the vessel while securely holding it.</p>	A 000			

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A 000	<p>Continued From page 28</p> <p>Preeclampsia is - a serious condition developing in late pregnancy that is characterized by a sudden rise in blood pressure, excessive weight gain, generalized edema, proteinuria, severe headache, and visual disturbances.</p> <p>PTT: Partial thromboplastin time (PTT) test is a blood test that helps doctors assess your body's ability to form blood clots</p> <p>Pyxis : is an automated medication dispensing system,</p> <p>STEMI: ST-Elevation Myocardial Infarction (STEMI) is a very serious type of heart attack during which one of the hearts major arteries (one of the arteries that supplies oxygen and nutrient-rich blood to the heart muscle) is blocked.</p> <p>TEE probe: A transesophageal echocardiogram, or TEE is an alternative way to perform an echocardiogram. A specialized probe containing an ultrasound transducer at its tip is passed into the patient's esophagus.</p> <p>TOLAC (trial of labor after cesarean) refers to the decision to attempt a vaginal delivery after a cesarean section.</p> <p>Transvenous cardiac pacing: also called endocardial pacing, is a potentially life saving intervention used primarily to correct profound bradycardia.</p> <p>VBAC: refers to a vaginal delivery that occurred after a prior cesarean.</p>	A 000		

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A 021 A 021	Continued From page 29 <b>COMPLIANCE WITH LAWS</b> CFR(s): 482.11(a)  The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.  This STANDARD is not met as evidenced by: The facility failed to maintain compliance with federal laws related to Occupational Safety and Health Administration (OSHA), ensuring safe practices in the use of chemicals.  Finding:  OSHA guidelines for Healthcare Wide Guidelines, Hazardous Chemicals states in part, "...Potential Hazards: Employee exposure to hazardous chemicals, such as pesticides, disinfectants, and hazardous drugs in the workplace.  Possible Solutions  OSHA requires that employers implement a written program that meets the requirements of the Hazard Communication Standard (HCS) to provide for worker training, warning labels, and access to Material Safety Data Sheets (MSDSs) ...  -Provide readily available Material Safety Data Sheets (MSDSs) for all hazardous chemicals.  -Train workers in potential chemical hazards and controls (engineering controls, work practices, PPE) necessary to prevent hazards in the work area [29 CFR 1910.1200(h)(3)].	A 021 A 021			

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A 021	<p>Continued From page 30</p> <p>-Clearly label as hazardous all hazardous chemicals such as those found in some soaps, disinfectants, and pesticides [29 CFR 1910.1200(f)].</p> <p>Provide appropriate PPE: (e.g., gloves, goggles, splash aprons) when handling hazardous dishwashing detergents and chemicals [29 CFR 1910.132]. For more information see Healthcare Wide Hazards - (Lack of) Personal Protective Equipment.</p> <p>Medical Services and First Aid: Where the eyes or body of any person may be exposed to injurious corrosive materials, provide suitable facilities for quick drenching or flushing of the eyes and body within the work area for immediate emergency use [29 CFR 1910.151(c)] ..."</p> <p>A tour was conducted of the warehouse at Hospital (2) on the morning of 9/21/2019 with Staff #557 and revealed the following:</p> <p>A. The facility's warehouse which houses hazardous chemicals did not have a decontamination shower area available in case of possible chemical exposure.</p> <p>Staff #S557, Supply Chain Manager stated in part, "We don't have a shower or sink that I know of."</p> <p>B. Facility Staff #S557 reported, he did not know where the Material Safety Data Sheets where in case of chemical exposure.</p>	A 021			

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A 023	<p><b>LICENSURE OF PERSONNEL</b> CFR(s): 482.11(c)</p> <p>The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the hospital failed to have a well-organized service in the Emergency Room with a plan of administrative authority and delineation of responsibilities for patient care in that the hospital directed and allowed 10 of 10 paramedics (Paramedic #499, Paramedic #500, Paramedic #501, Paramedic #502, Paramedic #503, Paramedic #504, Paramedic #505, Paramedic #506, 719 and 720) to function outside their scope of practice. (Scope includes: provide Advanced Life Support in the field (outside of the hospital) and function as an unlicensed personnel in the hospital) while providing patient care in a Healthcare Facility Setting.</p> <p>This failed practice were identified in 2 of 2 hospital campuses which utilize paramedics in the emergency center, and nurses and patient care technicians who provide care and service to patients receiving hemodialysis treatment.</p> <p>Findings:</p> <p>The hospital personnel list provided on 9/17/2019 included eight paramedics/EMT (emergency medical technician) Personnel #S499, Personnel #S500, Personnel #S501, Personnel #S502, Personnel #S503, Personnel #S504, Personnel #S505, and Personnel #S506 who were hired in July 2019 with the plan to train them to work in</p>	A 023			



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A 023	<p>Continued From page 32</p> <p>the Emergency Center of hospital (1) to perform patient care. On the list of all Emergency Staff on 9/17/2019, the 8 were classified with the Job Title: Paramedic/EMT.</p> <p>The Job Description for EMT/Paramedic as of date: 9/01/2019 states that the Paramedic "...Proficiently support the delivery of patient care services and assists in coordinating patient work flow...., Transports patients, including those requiring cardiac monitoring....,assists with diagnostic and therapeutic procedures...Assists in admitting, transferring, and discharging of patients... Performs assigned tasks in a timely manner with minimal patient discomfort...Technical Functions: Proficiently performs delegated technical functions, including but not limited to: a. Phlebotomy, b. EKG, c. Sterilization as applicable, d. Vision and hearing screenings as applicable, e. Point of care testing as applicable, f. Initiates intravenous lines, g. Attaches monitoring devices to patient as appropriate, h. Works under direct supervision of a physician, i. Recognizes and assists in emergency situations, and performs advance life support including electrical cardiac defibrillation or cardioversion as indicated. 'Direct supervision' means supervision of an emergency medical technician-paramedic or licensed paramedic by a licensed physician who is present in the same area or an area adjacent to the area where an emergency medical technician-paramedic or licensed paramedic performs a procedure and who is immediately available to provide assistance and direction during the performance of the procedure. 'Advanced life support' means health care provided to sustain life in an emergency, life-threatening situation."</p>	A 023			

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A 023	Continued From page 33  An interview was conducted with Personnel #S118 on 9/18/2019, at approximately 1:30 PM, in the Emergency Center. Personnel #S118 was asked about the use of Paramedics in the Emergency Center (EC). Personnel #S118 stated that they are used as unlicensed staff. Personnel #S118 was asked what could the Paramedics do in the EC. Personnel #S118 stated that they do the same duties as a Patient Care Technician (PCT). Personnel #S118 again was asked what the Paramedics were actually doing in the EC. Personnel #S118 said, they help with wheelchairs for the patients, they help with transport of a patient for special x-ray procedures or transport to the floor when admitted. Personnel #S118 said that they do venipuncture for point of care testing and start IV's. Personnel #S118 was asked if the PCT perform venipuncture for point of care testing and start IV's. Personnel #S118 stated that the PCT's do perform venipuncture after they have gone through training.  Personnel #S118 was informed that in the State of Texas, the Paramedic has a Scope of Practice that covers the duties on an ambulance and providing emergency medical care associated with an ambulance call; also in the State of Texas the Paramedic/EMT is considered an "unlicensed assistive personnel" (UAPs) when working in acute care settings, such as the ED.  Personnel #S118 stated that they had just started using their EMT/Paramedics in the EC and really do not know how it is going to go. Personnel	A 023			

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A 023	<p>Continued From page 34</p> <p>#118 was informed that the scope of service for the EMT's/Paramedics is limited to performing duties in the "pre-hospital and inter-facility transport" settings.</p> <p>An interview was conducted with Personnel #S309 on 9/24/2019, at approximately 11:30 a.m. in the Conference Room. Personnel #S309 wanted clarification about the Paramedics in the EC. Personnel #S309 had printed out the rules at Title 22 Part 9 Texas Medical Board Chapter 197 Emergency Medical Service.</p> <p>Review of the documents mentioned above were discussed with Personnel #309 and the same portion of this Title 22 ..."The BON ( Board of Nursing) delegation rules view EMT's, Paramedics or other similarly trained staff as 'unlicensed assistive personnel's (UAP's) when working in acute care settings, such as the ED."</p> <p>" The rules governing EMTs and Paramedics are located in Title 25, Texas Administrative Code, Section 157.2. This rule limits the scope of practice of EMTs/Paramedics to performing duties in the 'pre-hospital and inter-facility transport' settings...Therefore, whether certified or licensed, the BON delegation rules view EMT's, Paramedics, or other similarly trained staff as 'unlicensed assistive personnel' when working in acute care setting such as the ED...other laws outside of the BON's (Board of Nursing) jurisdiction may prohibit performance of certain tasks by unlicensed personnel, even if a physician is willing to delegate a task." Personnel #309 stated that she understood and would have to take care of this topic.</p>	A 023			

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A 023	Continued From page 35  TITLE 22 EXAMINING BOARDS, PART 9 TEXAS MEDICAL BOARD, CHAPTER 197 EMERGENCY MEDICAL SERVICE  RULE §197.7 Physician Supervision of Emergency Medical Technician-Paramedic or Licensed Paramedic Care Provided in a Health Care Facility Setting (provide Advanced Life Support in the facility)...Advanced life support--Health care provided to sustain life in an emergency, life-threatening situation...Direct supervision - Supervision by a licensed physician who is present in the same area or an area adjacent to the area where an emergency medical technician-paramedic or licensed paramedic performs a procedure and who is immediately available to provide assistance and direction during the performance of the procedure...a person who is certified as an EMT-P or a LP, is acting under the delegation and direct supervision of a licensed physician, and is authorized to provide advanced life support by a health care facility, may in accordance with DSHS rules provide advanced life support in the facility's emergency or urgent care clinical setting, including a hospital emergency room and a freestanding emergency medical care facility...The supervising physician may use protocols, which may include standing delegation orders. Such instructions may not be used in lieu of communication with the supervising physician or of obtaining the physician's physical assistance and direction during the performance of a procedure...The physician who delegates to and directly supervises advanced life support in a healthcare facility as authorized in this section remains professionally and legally responsible for	A 023			

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A 023	<p>Continued From page 36</p> <p>the patient care provided by the EMT-P or LP...The physician who delegates to and directly supervises an EMT-P or LP providing advanced life support must ensure that the EMT-P or LP meets all requirements under the law related to creating and maintaining a medical record documenting the patient encounter...adopted to be effective April 3, 2016, 41 TexReg 2315.</p> <p>The BON (Texas Board of Nursing) delegation rules view EMTs, Paramedics, or other similarly trained staff as "unlicensed assistive personnel" (UAPs) when working in acute care settings, such as the ED.</p> <p><a href="https://www.bon.state.tx.us/faq_delegation.asp#7">https://www.bon.state.tx.us/faq_delegation.asp#7</a> - Paramedics/EMTs in the Emergency Department (ED)...Can an RN delegate starting a peripheral IV saline lock to an EMT/Paramedic in the Emergency Department (ED)? Some of the "techs" in our ED are "licensed paramedics" who also work for EMS. What other kinds of tasks can be delegated to Emergency Medical Technicians (EMTs)/Paramedics in the ED setting...The rules governing EMTs and Paramedics are located in Title 25, Texas Administrative Code, Section 157.2. This rule limits the scope of practice of EMTs/Paramedics to performing duties in the "pre-hospital and inter-facility transport" settings ...Therefore, whether certified or licensed, the BON delegation rules view EMTs, Paramedics, or other similarly trained staff as "unlicensed assistive personnel" (UAPs) when working in acute care settings, such as the ED...The BON's delegation Rule 224 is not prescriptive to specific procedures or tasks that may or may not be delegated. Rule 224 permits an RN to delegate starting a peripheral IV saline lock to an unlicensed person providing all of the delegation</p>	A 023			

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A 023	Continued From page 37 criteria are met...Other laws outside of the BON's jurisdiction may prohibit performance of certain tasks by unlicensed personnel, even if a physician is willing to delegate a task."  TITLE 22 EXAMINING BOARDS, PART 11 TEXAS BOARD OF NURSING, CHAPTER 224 DELEGATION OF NURSING TASKS BY REGISTERED PROFESSIONAL NURSES TO UNLICENSED PERSONNEL FOR CLIENTS WITH ACUTE CONDITIONS OR IN ACUTE CARE ENVIRONMENTS...Rule §224.8, "Delegation of Tasks...Discretionary Delegation Tasks...the manner in which the unlicensed person demonstrates competency of the delegated task...the mechanism for reevaluation of the competency...periodic re-demonstration of competency...the following are nursing tasks that are not usually within the scope of sound professional nursing judgment to delegate...sterile procedures-those procedures involving a wound or an anatomical site which could potentially become infected...non-sterile procedures, such as dressing or cleansing penetrating wounds and deep burns...invasive procedures-inserting tubes in a body cavity or instilling or inserting substances into an indwelling tube; and care of broken skin other than minor abrasions or cuts generally classified as requiring only first aid treatment...Nursing Tasks Prohibited from Delegation By way of example, and not in limitation, the following are nursing tasks that are not within the scope of sound professional nursing judgment to delegate...physical, psychological, and social assessment which requires professional nursing judgment, intervention, referral, or follow-up...formulation of the nursing care plan and evaluation of the	A 023			

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A 023	<p>Continued From page 38</p> <p>client's response to the care rendered...the responsibility and accountability for client health teaching and health counseling (discharge instructions) which promotes client education and involves the client's significant others in accomplishing health goals; and administration of medications, including intravenous fluids, except by medication aides as permitted under §224.9 of this title (relating to The Medication Aide Permit Holder)..."</p> <p>Rule §224.5, "RN Accountability for Delegated Tasks The RN nurse administrator or the RN who is responsible for nursing services in settings that utilize RN delegation in clients with acute care conditions or acute care environments shall be responsible for knowing the requirements of this rule and for taking reasonable steps to assure that registered nurse delegation is implemented and conducted in compliance with the Texas Nursing Practice Act and this chapter..."</p> <p>Review of the Paramedics' Personnel Files documented training and competency evaluations revealed beyond the scope of practice for paramedics in the State of Texas:</p> <p>Paramedic #S499, Paramedic #S500, Paramedic #501, Paramedics #S502, Paramedic #503, Paramedic #504, Paramedic #505, Paramedic #506</p> <p>Completed the modules for:</p> <p>Hemorrhage Control module</p> <p>i-Stat General Post Test,</p>	A 023			

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A 023	Continued From page 39  Early Heart Attack Care,  Stroke Education/Activation,  Point of Care Testing Glucometer Module,  Point of Care Testing Pregnancy Manual Module,  Restraint Annual unlicensed,  Blood Component Transportation,  EMTALA (Emergency Medical Treatment and Labor Act) Training Medical Equipment Management.  Paramedic S#499, Paramedic #S500, Paramedic S#501, Paramedic #S502, Paramedic #S503, Paramedic #S504, Paramedic #505, Paramedic #506  Mandatory Education Acknowledgement included education and competency validation of the following topics: EKG (electrocardiogram) 12 Lead Module/Skill; Impulse Module V, NIH Stroke Scale, POCT (Point of Care testing) Glucometer Module/Skill, POCT iStat module/skill, POCT Pregnancy Manual Module/Skill, Restraints Module/Skill, and Suicide/Homicide Risk Education.  Paramedics S#499, Paramedic #S500, Paramedic S#501, Paramedic #S502, Paramedic #S503, Paramedic S#504, Paramedic S#505, Paramedic S#506	A 023			



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A 023	<p>Continued From page 40</p> <p>Competency based clinical orientation tool Titled : Nurse Education was completed: STEMI protocol, stroke protocol, hypoglycemia guideline, DKA guidelines.</p> <p>Paramedic #S503</p> <p>Verbalizes policies, guidelines, standard of care, and resources: intubation tray/cart, chest tube bundle, medications/expiration dates, suction, oxygen transport tank, and cardiac monitor/defibrillation supplies and moderate sedation.</p> <p>Paramedic S#499, Paramedic S#500, Paramedic S#501, Paramedic S#502, Paramedic S#505, Paramedic S#506</p> <p>Competencies check off : phlebotomy, peripheral IV insertion, cervical spine alignment, blood cultures, EKG's, manual ventilation with BVM (bag, valve, mask) and airway adjuncts, and POC testing.</p> <p>Paramedic S#499, Paramedic S#500, Paramedic S#501, Paramedic S#502</p> <p>Verbalizes policies, guidelines, standard of care, and resources: ventilator settings/troubleshooting, cardiac monitoring, internal paddles, external paddles, basic cardiac rhythm recognition, advanced rhythm recognition, synchronized cardioversion, transcutaneous/transvenous pacing, hemodynamic setup and monitoring/arterial line set-up, fluid resuscitation/rapid infuser, massive</p>	A 023			

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A 023	<p>Continued From page 41</p> <p>blood transfusion procedure and set-up, Cricothyroidotomy set up, thoracotomy set up. The trauma management: MVC (motor vehicle collision), gunshot wounds, stab wounds, amputation, crush injuries, head injuries, spinal cord injuries, fall victims, aggravated assault, sexual assault, chest trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation.</p> <p>Paramedic S#500</p> <p>Management of critical medical problems: Verbalizes policies, guidelines, standard of care and resources. Demonstrates the skill safely effectively, and efficiently: ingestion, chest pain, CVA (cardiovascular accident), congestive heart failure (CHF), shortness of breath, altered mental status, ESRD (end stage renal disease), sepsis, seizures, GI bleeds, cardiogenic shock, hypovolemic shock, neurogenic shock, septic shock, These were only Verbalized policies, guidelines, standard of care and resources: anaphylactic shock, obstructive shock, hypo/hyperthermic patients, DIC, DKA, pediatric trauma, pregnant trauma patients, geriatric patients, and psychiatric patients.</p> <p>Paramedic S#500, S#504, Paramedic S#505, Paramedic S#506</p> <p>Verbalizes policies, guidelines, standard of care and resources; Plus demonstrates the skill safely, effectively and efficiently: Moderate sedation, care and disposition of clothing and valuables, Death Care, Transportation of the ICU patient,</p>	A 023			

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A 023	<p>Continued From page 42 Transportation of the telemetry patient.</p> <p>Paramedic S#500, Paramedic S#502, Paramedic #S503, Paramedic #S504, Paramedic #S505, Paramedic #S506</p> <p>Verbalizes policies, guidelines, standard of care and resources; plus demonstrates the skill safely, effectively and efficiently: Notification of attending physician and documentation, Notification of primary RN and documentation, Shock Room throughput, Role of the Chief Resident, Role of the intern.</p> <p>Paramedic #500, Paramedic#502, Paramedic #503,Paramedic #S504</p> <p>Verbalize policies, guidelines, standard of care and resources: ACLS equipment, sterile trays, intubation tray/cart, chest tube bundle, medications/expiration dates, suction, oxygen transport tank, cardiac monitor/defibrillation supplies, pediatric crash cart, paramedic specific CBOT, Thoracotomy bundle, rapid response stretcher checklist, Shock room supply carts, Blue/intake/gold pod supply carts, Places work order, Stocks specialty supply carts (i.e. OB/GYN cart, supply cart, carts in 14), clean endoscope, cleans vaginal probe.</p> <p>Paramedic S#500, S#502, Paramedic S#504, Paramedic S#505, Paramedic S#506</p> <p>Demonstrates the skill safely, effectively and efficiently: sterile processing log/procedure, cardiac monitoring, manual blood pressure, basic</p>	A 023			

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A 023	<p>Continued From page 43</p> <p>cardiac rhythm recognition, advanced rhythm recognition.</p> <p>Paramedic S#500; Paramedic S#501, Paramedic S#502, Paramedic S#503, Paramedic S#504, Paramedic S#505, Paramedic S#506</p> <p>Demonstrates the skill safely, effectively and efficiently: phlebotomy, peripheral IV insertion, cervical spine alignment, blood cultures, EKG's, Manual ventilation with BVM (bag, valve, mask) and airway adjuncts, POC testing; cardiac monitoring;</p> <p>Paramedic S#500</p> <p>Verbalizes policies, guidelines, standard of care and resources: ventilator settings/troubleshooting, Internal paddles, external paddles, basic cardiac rhythm recognition, advanced rhythm recognition, synchronized cardioversion, transcutaneous/transvenous pacing, hemodynamic setup and monitoring/arterial line set-up, fluid resuscitation/rapid infuser, massive blood transfusion procedure and set-up, Cricothyroidotomy set up; thoracotomy set up.</p> <p>Paramedics S#502, Paramedic S#503, Paramedics S#504, Paramedic S#505, Paramedic S#506</p> <p>Verbalizes policies, guidelines, standard of care and resources and demonstrated the competency/skill: ventilator settings/troubleshooting, Internal paddles,</p>	A 023			

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A 023	Continued From page 44 external paddles, basic cardiac rhythm recognition, advanced rhythm recognition, synchronized cardioversion, transcutaneous/transvenous pacing, hemodynamic setup and monitoring/arterial line set-up, fluid resuscitation/rapid infuser, massive blood transfusion procedure and set-up, Cricothyroidotomy set up; thoracotomy set up, sterile processing log/procedure, phlebotomy, peripheral IV insertion, cervical spine alignment, blood cultures, EKG's, Manual ventilation with BVM (bag, valve, mask) and airway adjuncts, POC testing, cardiac monitoring, manual blood pressure, basic cardiac rhythm recognition, advanced rhythm recognition, ventilator settings/troubleshooting, cardiac monitoring, Internal paddles, external paddles, basic cardiac rhythm recognition, advanced rhythm recognition, synchronized cardioversion, hemodynamic setup and monitoring/arterial line set-up, fluid resuscitation/rapid infuser, massive blood transfusion procedure and set-up, thoracotomy set up, MVC (motor vehicle collision), gunshot wounds, stab wounds. Trauma management: head injuries  Paramedic S#502, Paramedic S#503, Paramedic S#504  Verbalized policies, guidelines, standard of care and resources Management of critical medical problems: ingestion, chest pain, CVA (cardiovascular accident), congestive heart failure (CHF), shortness of breath; altered mental status, seizures, GI bleeds, hypovolemic shock, neurogenic shock, septic shock, ESRD, anaphylactic shock, obstructive shock, hypo/hyperthermic patients, DIC, DKA, Pediatric	A 023			

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A 023	<p>Continued From page 45</p> <p>trauma, pregnant trauma patients, sepsis, geriatric patients, psychiatric patients.</p> <p>Paramedic S#500, Paramedic S#501, Paramedic S#504; Paramedic S#505, Paramedic S#506</p> <p>Demonstrates the skill safely, effectively and efficiently: Trauma management: MVC (motor vehicle collision), gunshot wounds, stab wounds, head injuries.</p> <p>Paramedic S#500, Paramedic S#501, Paramedic S#503</p> <p>Verbalized policies, guidelines, standard of care and resources: spinal cord injuries, fall victims, aggravated assault, sexual assault, chest trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation.</p> <p>Paramedic S#503</p> <p>Verbalized policies, guidelines, standard of care and resources: Ingestion, chest pain, CVA (cardiovascular accident), congestive heart failure (CHF), shortness of breath, altered mental status, seizures, hypovolemic shock, septic shock, ESRD, anaphylactic shock, DKA, Pediatric trauma, pregnant trauma patients, sepsis, geriatric patients, psychiatric patients.</p> <p>Paramedic S#500, Paramedic S#501, Paramedic S#505, Paramedic S#506</p>	A 023			

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A 023	<p>Continued From page 46</p> <p>Management of critical medical problems: Demonstrates the skill safely, effectively and efficiently: Ingestion, chest pain, seizures, GI bleeds, hypovolemic shock, anaphylactic shock, obstructive shock, hypo/hyperthermic patients, DIC, DKA; Pediatric trauma, pregnant trauma patients, geriatric patients, psychiatric patients..</p> <p>Paramedic S#503, Paramedic #504, Paramedic S#505, Paramedic S#506</p> <p>Demonstrates the skill safely, effectively and efficiently: Ingestion, chest pain, CVA (cardiovascular accident), congestive heart failure (CHF), shortness of breath, altered mental status, ESRD, sepsis, spinal cord injuries, fall victims, aggravated assault, sexual assault, chest trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation, spinal cord injuries, fall victims, aggravated assault, sexual assault, chest trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation.</p> <p>Paramedic S#504, Paramedic S#505, Paramedic S#506</p> <p>Demonstrates the skill safely, effectively and efficiently: Chest tube set-up, Central line placement set-up, Tourniquet application, Stabilization of fractures, pelvic binder, traction splint. Trauma management: MVC (motor vehicle collision), gunshot wounds, stab wounds, amputation, crush injuries, head injuries, spinal cord injuries, fall victims, aggravated assault, sexual assault, facial/dental trauma, chest</p>	A 023			

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A 023	<p>Continued From page 47</p> <p>trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation.</p> <p>Management of critical medical problems: ingestion, chest pain, CVA (cardiovascular accident), congestive heart failure (CHF), seizures, GI bleeds, cardiogenic sock, hypovolemic shock, neurogenic shock, septic shock, ESRD, anaphylactic shock, obstructive shock, hypo/hyperthermic patients, DIC, DKA, Pediatric trauma, pregnant trauma patients, sepsis, geriatric patients, psychiatric patients. Bolus fluids under delegation.</p> <p>Paramedic #S503</p> <p>Verbalizes policies, guidelines, standard of care and resources: spinal cord injuries, fall victims, aggravated assault, sexual assault, chest trauma, pelvic trauma, genitourinary trauma, extremity trauma, hanging/strangulation, drowning, burns and smoke inhalation.</p> <p>Record review of the job description "Emergency Medical Technician Paramedic (EMTP) dated 09/01/2019 states: Proficiently performs delegated technical functions including not limited to Phlebotomy, initiates intravenous lines</p> <p>Record review of Hospital #2 of the scope of practice for the EMT-Intermediate/Paramedic Checklist revealed the following skills and tasks that must be completed with countersigning by the preceptor prior to being released from orientation revealed some of the task on the list that included:</p>	A 023			



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A 023	<p>Continued From page 48</p> <ul style="list-style-type: none"> <li>o Peripheral IV insertion,</li> <li>o Blood cultures,</li> <li>o Defibrillation,</li> <li>o Transcutaneous/Transvenous Pacing,</li> <li>o Internal and external paddles (adults and pediatric patient),</li> <li>o Fluid administration: bolus fluids under delegation.</li> </ul> <p>Record review of the Patient Care Technicians competency, dated April 2019 revealed: No invasive task such as IV insertion, blood culture, fluid administration, pacing, or use of internal/external paddles noted on the competency.</p> <p>Staff (ID # S719), Paramedic's checklist was completed on 07/02/2019.</p> <p>Staff (ID # S720), Paramedic's checklist completed on 09/10/2019.</p> <p>Interview on 09/24/2019, at 10:15 a.m., with RN Director, Staff (ID #S354) who stated, "Critical care used the EMT's, as techs (Patient Care Technicians). We are starting a critical care transport team, they are still in the training. We are a level III and Hospital (1) is a level II. We will not have to depend on our vendors for our STEMI's and Stroke patients to transport these patients."</p>	A 023		

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A 023	Continued From page 49  Interview on 09/24/2019, at 1:55 p.m., with a Paramedic Staff (ID# S719) stated, "I draw blood and IV (intravenous) and depends on where I am working or what the RN's need from us."  Review of training records in the personnel file for Staff # S199, revealed last hemodialysis department checklist completed 11/11/13.  Review of Staff #S195, Hemodialysis RN Orientation checklist was completed on 10/11/11. No further Hemodialysis skills checklist completed.  Review of staff #S193, Hemodialysis RN orientation checklist completed on 10/04/17 no further training completed.  No water training or skills checklist identified for Staff #S193 and #S195, and both are responsible for daily water checks.  Interview with Staff #S191 stated, the department recognized the area for improvement in competency, skills, and water checklist and had Marcor in the facility on 9/17/2019 for a mandatory in-service, but did not complete a return back demonstration of competency on any of the participants.	A 023			
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	A 043			

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A 043	<p>Continued From page 50</p> <p>for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ...</p> <p>This CONDITION is not met as evidenced by:</p> <ol style="list-style-type: none"> <li>Based on record reviews, interviews, and observation, an Immediate Jeopardy situation was called on September 25, 2019, at 10:30 a.m., at Hospital 2 Labor and Delivery Obstetric Care Unit. The hospital's Medical, Anesthesia, and Nursing staff failed to effectively communicate amongst themselves concerning a critical situation with one obstetric patient. The failure of the medical team to identify this critical event during the provision of care to this patient led to a negative outcome of Patient #429. This failed practice has the potential to affect obstetric patients receiving prenatal care, including labor and delivery in Hospital 2.</li> <li>Based on record reviews, interviews, and observation, Hospital 2 Obstetric Care (Triage and Labor and Delivery Units) failed to follow the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN) Staffing Needs Standards by not ensuring that they had the appropriate number of nurses to care for obstetric patients in those two units. This failed practice creates the likelihood for negative outcomes for mother and fetus/child. Hospital 2 adopted the AWHONN guidance as a hospital Policy for staffing the Obstetric Triage Unit, Labor and Delivery Unit, and Antepartum/Post-partum Unit.</li> <li>Based on record reviews, interviews, and observations, Hospital 2 Obstetric Unit failed to have the required number of Intravenous pumps</li> </ol>	A 043			

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A 043	<p>Continued From page 51</p> <p>to provide quality care to two patients. Patient (A) with pre-eclampsia who needed Magnesium Sulfate and Patient (B) who needed a Pitocin induction due to non-reassurance fetal monitor heart rate. This failure placed mothers and fetuses at risk for fetal distress and created the likelihood of a patient developing seizures (pre-eclampsia) which can result in the death of mother or baby.</p> <p>4. Pre-eclampsia: Hypertensive disorders of pregnant women complicate up to 10% of pregnancies worldwide, constituting one of the greatest causes of maternal and perinatal morbidity and mortality worldwide. As leaders in women's health care, ob-gyns play a leading role in the prevention, diagnosis, and treatment of hypertension in pregnancy and preeclampsia. Preeclampsia is a serious condition that typically starts after the 20th week of pregnancy, high blood pressure is a main contributing factor. The rate of preeclampsia in the US has increased 25% in the last two decades and is a leading cause of maternal and infant illness and death. The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine continue to support the short-term (usually less than 48 hours) use of magnesium sulfate in obstetric care for appropriate conditions and for appropriate durations of treatment, which includes the prevention and treatment of seizures in women with preeclampsia or eclampsia. (American College of Obstetrics &amp; Gynecology ACOG, December 2018).</p> <p>Labor can be induced via medications or other methods that stimulate uterine contractions so that a woman may attempt a vaginal birth. The</p>	A 043			

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A 043	<p>Continued From page 52</p> <p>ob-gyn may recommend induction if the pregnancy is post term or if the health of the mother or fetus is at risk. (ACOG, 2017)</p> <p>5. Hospital #2's Obstetric Care (Triage and Labor and Delivery Units) failed to follow the AWHONN Staffing Needs standards by not ensuring that they had the appropriate number of nurses to care for the obstetric patient in those two units. This failed practice creates the likelihood for negative outcomes for mother and fetus/child.</p> <p>6. Based on observation, interviews, and record review, Hospital 2 failed to follow AWHONN standards for management of patient with Pitocin drip. This failed practice can affect patients admitted to the Labor and Delivery Unit for Pitocin Induction or Pitocin Augmentation.</p> <p>7. Based on review of documents and interview, the Governing Body failed to provide effective oversight of the Nursing Department. The Governing Body failed to ensure all policies, plans, reports requiring Governing Body review, and by-laws written and implemented by the Nursing Department were reviewed, approved, and/or adopted by the Governing Body.</p> <p>8. Based on record review and interview, the Governing body failed to designate specific individuals as QMP (Qualified Medical Professional) that would be performing medical screening examinations in the emergency department.</p>	A 043		

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A 043	Continued From page 53  9. Based on record review and interview, the governing body did not approve the QMP to complete Medical Screening Exam (MSE) in Hospital #2 in two of two medical personal assigned to the ED.  10. Based on record review and interview, the governing body failed to specify in the medical staff rules, regulations, and bylaws what the qualifications were for an individual to perform a medical screening examination. Furthermore, the governing body did not designate individuals who were qualified to perform a medical screening examination to patients presenting to the emergency center.  Findings:  Patient #429, Medical Record Review:  Patient #429 was a Gravida 2 Para 1 (Two pregnancy and one live child). During the hospital Obstetric Screening on 06/10/2019, the patient indicated that she was pregnant but did not know how many weeks of gestational age. During this appointment, the patient was given basic prenatal information. On 06/17/2019, Patient #429's History and Physical were completed. The provider indicated that the Estimated Date of Delivery was 09/26/2019. It was confirmed by ultrasound that the patient was at 22 weeks gestational age. The History and Physical revealed that the patient had a previous cesarean section. During the current pregnancy, she was diagnosed with Gestational Diabetes Mellitus (A1GDM).	A 043			

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A 043	<p>Continued From page 54</p> <p>During the prenatal visit on 06/10/2019, the patient revealed that she had a Cesarean Section in 2010. The provider who evaluated the patient wrote that the patient was unsure why or in what hospital the Cesarean Section was performed. She was 38 gestational weeks when labor was attempted. Provider indicated, she had a low transverse. The provider's notes during this visit indicated that the patient wanted a Trial of Labor and will continue to discuss.</p> <p>Trial of labor after Cesarean Section) (TOLAC) is a planned or attempted vaginal birth after cesarean (VBAC). Sometimes, there is a need to change the plan, and a TOLAC results in cesarean birth after cesarean (CBAC). A birth is officially considered a VBAC once the TOLAC results in a vaginal delivery. (<a href="https://www.uchicagomedicine.org">https://www.uchicagomedicine.org</a>)</p> <p>A TOLAC is the attempt to have a VBAC. If it is successful, TOLAC results in a vaginal birth. If it is not successful, you will need another cesarean delivery. (The American College of Obstetrics &amp; Gynecologist, FAQ070, December 2017)</p> <p>The patient was also seen on 06/17/2019 and was diagnosed with Gestational Diabetes during this visit. She was placed on close monitoring with Finger Blood Sticks for glucose level five times a day. At this time, there were no indications that the provider asked details of the previous cesarean section but the plan for TOLAC continued.</p>	A 043			

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A 043	<p>Continued From page 55</p> <p>During the prenatal visit of Patient #429, there were no indications that the obstetric provider attempted to speak to the patient concerning the reason(s) why she had a previous cesarean section during her first pregnancy and in what hospital it was performed. They proceeded with the Trial of Labor delivery plans.</p> <p>On 9/12/2019, Patient #429 arrived at Hospital 2 at 4:41 am. Medical records revealed that the patient went to the Obstetric Triage Unit where she was evaluated by the nursing staff. The patient's pulse was taken and recorded as 141 beats/per minute. A pulse of 141 is indicative of tachycardia. Tachycardia, also called tachyarrhythmia, is a heart rate that exceeds the normal resting rate. In general, a resting heart rate over 100 beats per minute is accepted as tachycardia in adults. (<a href="https://en-wikipedia.org">https://en-wikipedia.org</a>).</p> <p>Maternal tachycardia is defined as a baseline heart rate greater than 100 bpm. Anxiety, a low-grade temperature elevation, fever, and chorioamnionitis have been associated with an MHR between 100 and 130 bpm (Yamashiro et al., 1988). This rare arrhythmia started and stopped spontaneously, could not be predictably induced or terminated, and increased the risk of tachycardia-induced congestive cardiomyopathy and heart failure (Kam, Lee, &amp; Teo, 1994). When the tachycardic MHR baseline approaches 140 bpm, it may flatten, especially when a woman is diabetic and/or hemodynamically or metabolically unstable.</p>	A 043			



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A 043	Continued From page 56  According to the Medical History recorded on 09/12/2019, at 4:43 am (during the patient's admission to Labor & Delivery), the Obstetric (OB) attending Physician #S714 indicated that the patient denied having Diabetes Mellitus during this pregnancy. However, record review showed that the patient had been diagnosed with Diabetes Mellitus since her 20th gestational week. The patient had been taking Metformin (an oral diabetes medicine that helps control blood sugar levels) with doses of 1,000 milligrams in the morning and 500 milligrams in the afternoon for the treatment of Gestational Diabetes Mellitus. During this medical encounter, the provider stated "There were no vitals taken for this visit". Vaginal examination at this time was C/C/0. (Cervix is completely dilated, complete effacement, and the baby's presenting part is at 0 station). Obstetric provider still recognized that the patient is a TOLAC. The OB Attending documented that the patient was not on pain management for labor.  During the admission, laboratory tests were ordered at 4:39 am for CBC ( complete blood count), Type and Screen, Hepatitis B, Rubella, and Urinalysis. Patient uterine contractions were from 1 to 2 per minutes. The patient was verbally consented by the OB provider for a TOLAC as she was having an intravenous access. Provider documented that the patient was in too much pain to sign the consent form. The provider also indicated that an interpreter was on the phone for the Spanish translation of the consent. During this encounter OB Resident S713 was present.  Record review indicated that at the time of	A 043			

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A 043	<p>Continued From page 57</p> <p>admission the patient gestational age was 38 weeks. A cervical examination at 4:46 A.M. was C/C/0 (Cervix dilation complete, effacement complete, and fetus presenting part is at 0 station. The Patient was spontaneously pushing. At 3:00 am, the patient indicated that her amniotic sac ruptured. There was no mention of the color of the amniotic fluid in this provider's notes. The care of the patient at this time were provided by attending OB S714 and OB Resident #S713.</p> <p>According to record review, at 4:29 am, the Spanish-speaking Labor and Delivery Nurse #S707 was trying to obtain verbal consent for delivery after an attempt to get this done over the phone failed. During this time, the patient was having contractions and Fetal Heart Tones were 150's. The record review of the Fetal Monitor strip showed the patient was contracting once every minute.</p> <p>According to records, at 4:30 am, the patient stated, she wanted to push. Nurse #S710 and S708 were present as admitting Labor and Delivery Nurses. Record review of the Labor and Delivery progress notes indicated that at 4:30 am, the patient stated she had a history of Diabetes and Hypotension.</p> <p>At 4:39 am, the patient was officially admitted to the Labor and Delivery unit for TOLAC.</p> <p>At 4:41 am, patient's heart rate continued at 138 per minute. Fetal Heart Tones 143-155 per minute. Reactive fetal monitor strip. OB Resident</p>	A 043			

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A 043	<p>Continued From page 58</p> <p>#S713 documented, "Notified of increased maternal rate, and unable to obtain an initial blood pressure due to patient actively pushing".</p> <p>At 4:43 am, maternal heart rate was 131 per minute. Glucose level out of range as 121 mg/dl (Range 74-106). The patient continued pushing and complaining of pain.</p> <p>At 4:45 am, maternal heart rate dropped to 28 per minute and back up to 141. Fetal Heart Tones were 120 to 143 per minute. Positive variability. Mother continued pushing with no pain management.</p> <p>The Patient was diagnosed to be positive for Group B strep (GBS) during her prenatal visit. The plan was to administer intravenous antibiotics during the second stage of labor to protect the new born. An order for Penicillin G potassium 4 million units was ordered to be infused at 4:45 am. Group B Streptococcus (GBS) is a type of bacterial infection that can be found in a pregnant woman's vagina or rectum. This bacteria is normally found in the vagina and/or rectum of about 25% of all healthy adult women. Women who test positive for GBS are said to be colonized. A mother can pass GBS to her baby during delivery. (<a href="https://americanpregnant.org">https://americanpregnant.org</a>).</p> <p>At 4:46 am, maternal heart rate was 139 to 143 per minute and Oxygen Saturation was 99%. Fetal Heart Tone 140's.</p>	A 043			

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A 043	<p>Continued From page 59</p> <p>At 4:49 am, maternal heart rate was 139 to 144 per minute. Fetal Heart Tones 120's with accelerations to 150 per minutes. Patient continued pushing with each contraction.</p> <p>At 4:50 am, maternal heart rate was 125 to 131 per minute. Fetal Heart Tones 130's. Attending OB #S714 prompted the patient to push during the contractions and noted that there was minimal fetal head descend.</p> <p>From 4:51 am to 4:53 am, the maternal heart rate was 140-145 per minute and Oxygen saturation was 98%. Fetal Heart Tones were 130's to 150's per minute.</p> <p>At 4:56 am, maternal heart rate was 141-152 per minute. Fetal Heart Tones 120's-130 per minute.</p> <p>At 4:58 am, maternal heart rate was 161 per minute. Fetal Heart Tone were 130's.</p> <p>At 5:00 am, maternal heart rate was 162 per minute. The first note appeared assessing the uterine contractions by palpation. Nurse #S708 indicated that the uterine relaxation was soft. Contractions were moderate every 1 to 2 minutes. Duration of the contraction was from 50 to 90 seconds. At 5:00 am, a Nursing Assessment completed by Nurse #708 indicated that the cardiac assessment was WDL (Within Defined Limits). However, the patient had been in tachycardia since 4:41 am.</p>	A 043			

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A 043	Continued From page 60  At 5:01 am, maternal heart rate was 159 per minute. Oxygen saturation 86%. If a pulse oxymeter measured a blood oxygen level (SpO2), a normal reading is typically between 95 and 100 percent. ( <a href="https://www.healthline.com">https://www.healthline.com</a> ).  At 5:05 am, maternal heart rate was 159 per minute. Maternal Oxygen saturation dropped from 86% to 68%. Fetal Heart Tones were 120's on external monitoring. The laboratory blood collection that was ordered at 4:39 am for CBC, Type and screen, Hepatitis B, Rubella, and IgG (immunoglobulin) were collected at 5:05am. At this time maternal heart rate dropped to 70.  At 5:09 am, maternal heart rate was 143 to 146 per minute. Fetal Heart Tone base line dropped to 120, Fetal Heart Tones to 115-119.  At 5:11 am, maternal heart rate was 154 per minute. Fetal Heart Tone 119-120 per minute. Patient continued pushing with no progress.  At 5:15 am, maternal heart rate was between 60 for few seconds and rising to 144 per minute. Fetal Heart Tones from 90's to 115 per minute. Patient continued pushing.  At 5:17 am, maternal heart rate was 144-147 per minute. Medication was ordered for Butorphanol (Stadol) 2 milligrams injection, however, it was discontinued and not administered. This is an	A 043			

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A 043	<p>Continued From page 61</p> <p>analgesic medication frequently used during active labor. From 5:18 am to 5:25 am, maternal heart rate was from 81 and fast rising to 164 per minute. Fetal Heart Tones from 115 to 120's on external monitor. Patient continued pushing with minimal descent noted. Attending MD #S714 indicated that there are some fetal Heart Tone decelerations.</p> <p>At 5:27 am, maternal heart rate was 146 per minute. Fetal Heart Tones were 120's with decelerations to the 110's. Reactive. At this time the Certified Registered Nurse Anesthetist (CRNA) S715 was called to consent patient for anesthesia.</p> <p>At 5:30 am, maternal heart rate was 152 per minute. At 5:31 am, OB Resident #713 was at bedside pushing with patient. From 5:31 am to 5:34 am, maternal heart rate continued in tachycardia at a rate of 152-157 per minute. Fetal Heart Tones 115.</p> <p>At 5:34 am, the laboratory results for the CBC were abnormal with WBC 13.3 K/uL (Range 4.5-11.0).</p> <p>At 5:36 am, maternal heart rate was 176 and Oxygen saturation 84%.</p> <p>At 5:38 am, maternal heart rate was 182. Fetal Heart Tones were 125 per minute with variable decelerations noted.</p>	A 043			

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A 043	<p>Continued From page 62</p> <p>At 5:39 am, the attending OB (Attending S714) returned to patient's room and announced that a caesarian section needed to be performed due to failure to descend. The (Attending S714) did not discuss the patient has been in tachycardia for over an hour. The Attending MD documented for the first time that when patient ruptured at home, the amniotic fluid was clear. There is no medical documentation of the patient being tachycardia and Oxygen saturations had been as low as 68%.</p> <p>At 5:41 am, the attending OB (MD S714) notified the CRNA (S715) that the patient's laboratory results were not back and gave the "OK" to proceed with the operating room.</p> <p>Record review of the anesthesia assessment revealed that the patient had a history of hypertension. From the time of the patient's arrival, admission, treatment, and arrival at the operating room, there was no blood pressure or temperature documented as taken. There was not any type of consultation with other providers to identify the medical reason for the patient's persistent tachycardia. The patient had indicated that she had high blood pressure during admission to the Labor and Delivery Unit. The first time the patient's blood pressure was taken was in the operating room by the CRNA at 5:50 am. BP showed in the anesthesia report as 90's/40's and dropping to the 40's. Maternal heart rate remained above 130.</p> <p>At 5:51 am, the patient went under anesthesia for a caesarian section. Baby was delivered at 5:55</p>	A 043			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>450289</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>09/27/2019</b>
NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 043	<p>Continued From page 63</p> <p>am. Placenta was delivered at 5:56 am intact. According to the anesthesia records dated 9/12/2019, Patient #429 was administered Vasopressin at 6:15 am, 6:20 am, and 6:30 am by the CRNA. Anesthesiologist on duty was MD #S716. At 6:00 am, estimated blood loss was 1000 ML.</p> <p>At 6:37 am, a Quick Note from MD #S716 indicated that there was an improvement in the patient's Blood Pressure (BP) after the second liter of fluids and no additional bleeding was noted and she no longer required vasopressors.</p> <p>At 6:52 am, abnormal laboratory results for the patient were: Hemoglobin level 8.5 g/dl (Range 12-16), Hematocrit POC: 25.0% (Range 37.0-47.0). Low values for both which may indicate bleeding.</p> <p>At 7:10 am, assessment completed by Nurse #708 indicated that the fundus was firm at the umbilicus.</p> <p>At 7:20 am, patient's vital signs were recorded as BP 51/34, Pulse 144 per minute, and Temperature 97.3F. This is the first temperature recorded. No indication that the Obstetric Medical Team has been notified of the patient's BP or Pulse.</p> <p>At 7:30 am, patient was taken by the anesthesia team to the OB Post Anesthesia Care Unit. Record review showed that the anesthesia team</p>	A 043			



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A 043	<p>Continued From page 64</p> <p>gave a verbal post-operative report to the OB Nurse #S708 who was responsible for the post anesthesia care and obstetric post-partum assessments.</p> <p>At 7:35 am, patient's vital signs were: BP 64/44, Pulse 144, and Respiration 33 per minute. Within the normal limit for the post-partum checks with uterine fundus firm at the umbilicus, done by Nurse #S708. CRNA #S715 reported patient systolic BP of 78 and pulse of 135. The CRNA administered 500 ml intravenous bolus and 250 ml 5% albumin. Reported patient's heart rate as 122 with 90 systolic blood pressure. Also ordered a hematocrit and hemoglobin. At 7:50 am, patient's vital signs were: Pulse 135, Respirations 32, and BP 99/54.</p> <p>At 7:38 am, medical order for pain with Toradol 30 mgs injectable. Patient rated her pain as an 8 (Scale from 0-10).</p> <p>At 7:39 am, Anesthesia Care ended.</p> <p>At 8:05 am, patient's vital signs were: Pulse was 146, Respirations 26, and BP 77/52. No indications that the RN notified the OB Medical team.</p> <p>At 8:13 am, Toradol 30 mgs injectable was administered.</p> <p>At 8:35 am, patient's vital signs were: Pulse was</p>	A 043			

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A 043	<p>Continued From page 65</p> <p>160, Respirations 28, and BP 58/33. No indications that the RN notified the OB Medical Team. The patient continued in tachycardia and hypotension.</p> <p>At 8:38 am, abnormal laboratory results: Hemoglobin 6.2 g/dl (Range 12-16.0) and Hematocrit 19.3% (Range 37.0-47.0) These results are lower than the ones from 6:52 am.</p> <p>At 8:45 am, was the first time that the OB Medical Team came to assess the patient's condition. OB provider conducted a vaginal examination and a manual extraction of a large amount of bright red blood and clots.</p> <p>At 8:46 am, Hemobate was administered. Hemobate or Carboprost is used to treat severe bleeding after childbirth (postpartum). (<a href="https://xrlist.com">https://xrlist.com</a>).</p> <p>At 8:47 am, anesthesia at bed side. No one from the OB Medical Team or the anesthesia team evaluated the patient's tachycardia status that had been present since 4:41 am.</p> <p>Medical Records reviewed revealed, that from 8:47 am through 10:00 am, the OB Medical team and Anesthesia Team continued providing different medical intervention. At 9:05 am, the patient received one unit of Pack Red Blood Cells. Massive Transfusion Protocol was activated. At 9:21 am, the OB Team and Anesthesia Team requested to take the patient to</p>	A 043			

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A 043	<p>Continued From page 66</p> <p>the operating room.</p> <p>Blood work was ordered at 8:52 am, for PT/PTT/Fibrinogen/ABG's and at 10:00 am, the OB Medical Team inserted an intrauterine balloon in an attempt to control the vaginal bleeding. During the recovery care the balloon fell off.</p> <p>At 10:23 am, the patient's vital signs were: Pulse was 175, Respirations 33, and BP 58/23. The OB Medical Team continued treating the patient's bleeding, however, there were no other medical services consulted to assist in stabilizing the hemodynamic status on this patient. Estimated blood loss of 3,000 ml.</p> <p>At 10:20 am, laboratory test D-DIMER was collected. D-dimer (or D dimer) is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. It is so named because it contains two D fragments of the fibrin protein joined by a cross-link. (<a href="https://wikipedia.org">https://wikipedia.org</a>). The blood work that was ordered at 8:52 am, was collected at 10:20 am.</p> <p>At 10:23 am, the patient continued in critical condition with a BP of 58/23 and Pulse of 175. New order for Red Blood Cell transfusion.</p> <p>At 10:44 am, a 12 lead EKG was ordered and a Chest X Ray. The patient was in persistent tachycardia and hypotension for over 6 hours. During the survey on 9/23/2019 and 9/24/2019, the OB staff was not able to show that the 12 lead EKG had been done on this patient as ordered.</p>	A 043			

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A 043	Continued From page 67  At 10:52 am, Hemobate 250mcgs was ordered for the second time and Methergine 0.2 mgs. At 11:00 am, this order was discontinued. The uterotonic effect of Methergine is utilized after delivery to assist involution and decrease hemorrhage, shortening the third stage of labor. Methergine® (methylergonovine maleate) may be administered orally for a maximum of 1 week postpartum to control uterine bleeding.  At 11:03 am, the Full Code order was discontinued. At 11:23 am, patient was placed in mechanical ventilator. At 11: 25 am, the Massive Blood Transfusion Protocol was activated for the second time. At this time the patient's BP was 116/85 Pulse 115.  At 11:41 am, the results of the PT/PTT were abnormal: PT 19 seconds (Range 11.8-15) and PTT 39.6 seconds (Range 23.6-36.4). Fibrinogen: 82 mg/dl (low) (Range 200-500). A prolonged PT means that the blood is taking too long to form a clot. This may be caused by conditions such as liver disease, vitamin K deficiency, or a coagulation factor deficiency (e.g., factor VII deficiency). The PT result is often interpreted with that of the PTT in determining what condition may be present. ( <a href="https://labtestonline.org">https://labtestonline.org</a> ). Low fibrinogen levels can also cause thrombosis due to an increase in coagulation activity. Acutely low levels are often related to conditions in which fibrinogen is used up more quickly than the body can produce it. This can occur with disseminated intravascular coagulation (DIC) and abnormal fibrinolysis,	A 043			

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A 043	<p>Continued From page 68</p> <p>which occurs when the body is overactive in breaking down and clearing blood clots. (<a href="https://labtestonline.org">https://labtestonline.org</a> March 2019.)</p> <p>At 11:46 am, the patient's temperature dropped to 92.8 degrees Fahrenheit, BP 86/59, and Pulse 128. The thermometer is an internal device that is part of the Foley catheter. At 11:54 am, the patient's temperature continued at 92.8 degrees F, BP 74/44 and Pulse 155. Between the hours of 12:06 pm to 2:00 pm, the patient remained tachycardic, hypotensive, and on ventilator support. The OB Medical Team discussed with the patient's family the patient critical condition and the medical need for a hysterectomy.</p> <p>The record indicated the Patient was taken to the operating room for a hysterectomy. At 2:43 pm, after the surgical procedure was completed, the patient went in cardiac arrest. Chest compressions were performed. The surgical field was re-inspected by the OB Medical team and there was not active bleeding. At this time the OB Team decided to call General Surgery to come in the operating room to evaluate the patient. The General Surgical Team noted a laceration of the right lobe of the liver and it was noted to be pulsatile bleeding. According to record review, even when General Surgical Team applied compression over the laceration the bleeding persisted. At 3:38 pm, the patient was pronounce dead.</p> <p>Medical record review indicated that the patient post-operative diagnosis were: Prior cesarean section due to arrest to descend,</p>	A 043			

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A 043	<p>Continued From page 69</p> <p>non-reassurance Fetal Heart Tones, Gestational Diabetes Mellitus, Post-partum hemorrhage, hemorrhagic shock, and cardiac arrest.</p> <p>On 9/25/2019, at 8:00 am, a group interview was conducted with 10 staff members who were present during Patient #429 critical event. Staff present during the interview were:</p> <ol style="list-style-type: none"> <li>1. Director of Nursing #S706</li> <li>2. Clinical Nurse Manager #S707</li> <li>3. Nurse #S708</li> <li>4. Administrator Director of Nursing #S709</li> <li>5. Hospital 2 Chief Nursing Officer #S331</li> <li>6. Nurse Clinician #S710</li> <li>7. OB Resident #S713</li> <li>8. Chief Nurse Executive #S712</li> <li>9. Chief of Obstetrics and Gynecology #S711</li> <li>10. Attending OB Physician #S714</li> </ol> <p>During the interview, it was asked why the patient was offered a TOLAC without having a complete obstetric history. Staff S711 indicated that it was not clear why the patient did not want to give that information. The doctor stated that her OB Medical staff missed to bring the question during the patient's prenatal visits.</p>	A 043			

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A 043	Continued From page 70  Nurse S708 who was present during the patient's initial assessment in the Triage Unit, stated that the temperature and blood pressure were not taken because the patient was uncomfortable. The Nurse indicated that when the patient was admitted to Labor and Delivery, they tried to do the blood pressure but every time the blood pressure machine would start the patient would have a contraction. When asked if the Triage Unit have a tympanic thermometer or any other type of thermometer, the Nurse stated, "no". When asked why a manual blood pressure was not taken, the Nurse stated, "I did not think about that". When asked if the OB Medical Team was notified of the patient's elevated heart rate, the Nurse stated, "no". Nurse #708 was asked if she notified the Attending OB physician on the patient's low blood pressure readings, the Nurse stated, "I thought anesthesia was taking care of that".  Staff S714 was the attending OB MD who admitted the patient to the Labor and Delivery Unit. She stated that she was in the operating room with another patient when she was notified by OB Resident MD S713 that the patient was complete and ready to push. Staff S714 stated that the OB Resident gave her the wrong information. The OB Resident #S713 communicated to Staff S714 that the patient had a cesarean section with the first child, a successful vaginal delivery, and would have been the second vaginal delivery. However, this patient was a TOLAC which means that this will be her first vaginal delivery. When the attending OB MD was asked if she had the correct information what she would have guided the OB	A 043			

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A 043	<p>Continued From page 71</p> <p>Resident to do. The attending OB MD stated, based on her vaginal examination I would have probably given her something for pain until she completed the case she was working on the operating room. Nurse S708 stated that she did not mention to the OB MD S714 that the patient was in tachycardia. Staff S714 stated that she did not notice the patient's heart rate until CRNA #S715 mentioned to her before the surgery. The doctor stated she missed that critical element.</p> <p>When asked if they noted that the patient was still tachycardia after delivery, Nurse S707 stated, "No, I was just doing the post-partum checks, I though the anesthesiology was keeping the OB doctors inform about the patient status". Staff S714 stated that she was unaware that the patient was unstable. She indicated that the anesthesia team did not communicate with her during the cesarean section surgery and that the patient was hypotensive and tachycardic during the surgery and during post anesthesia care. She was notified by the nurse that the patient was bleeding. That was the first time she became aware of the patient's hemodynamic status. Staff S714 stated, she did not know that during the cesarean section, the anesthesia team was administering medications to support the patient's blood pressure.</p> <p>When asked if the order for the 12 lead EKG was carried out, Staff S714 stated, "I am not sure". When asked if a blood transfusion reaction was called and investigated, the MD stated, "no". When asked if another medical service such as Internal Medicine or Cardiology were consulted to assess the patient's hypotension and tachycardic</p>	A 043			



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A 043	<p>Continued From page 72 status, the MD stated, "no".</p> <p>During the interview, the Chief of Obstetrics and Gynecology S711 was asked what were the opportunities that were missed during this patient's management, the Chief stated, "There were many opportunities missed. The temperature and blood pressure during the admission, missed communication between the OB Resident and the attending physician, missed communication between anesthesia team during and after the surgery, missed communication between the nurses and the attending physician, we missed the opportunity to have another medical specialty evaluate the patient prolonged tachycardia". The Chief of Obstetrics and Gynecology stated that the entire team need to develop a plan to address the obstetric patient needs including cardiovascular needs. The Chief also stated that the hospital delivered about 300 patients a month and most of them are high risk OB patients due to diabetes, hypertension, drug addiction, and other conditions that are common on this population.</p> <p>Interview and record review revealed Hospital 2 adopted the AWHONN guidance as a hospital Policy for staffing the Obstetric Triage Unit, Labor and Delivery Unit, and Antepartum/Post-partum Unit.</p> <p>On 9/23/2019, at 9:30 am, a hospital tour was conducted of the Triage Obstetric Care Unit. The Triage Unit has 8 beds. Patients observed needed to be assessed to verify that they were in active labor and monitored on this unit, as well as</p>	A 043			

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A 043	<p>Continued From page 73</p> <p>patients scheduled for caesarian section. Any other obstetric patient needing medical assessment would also be evaluated in this unit. During the tour, only one Registered Nurse was observed monitoring the Triage Care Unit. RN #S708 was with one RN who was on orientation.</p> <p>On 9/23/2019, at 10:00 am, RN #S708 was interviewed. She stated that the second RN went to the operating room with a patient needing a caesarian section. She stated that the Triage Unit is usually busy during the day and it slows down in the evenings. The RN indicated that there were always two RN's scheduled to work in the Triage Unit but during the day that does not always work.</p> <p>PITOCIN ADMINISTRATION</p> <p>On 09/24/2019, at 10:30 am, an observation was made in the Labor and Delivery. There were two nurses on duty, each was assigned to take care of two patient on Pitocin drip for induction/augmentation.</p> <p>On 09/25/2019, at 21:10 am, an interview was conducted with Nurse Manager #S707. During the interview, the manager confirmed the nurses were managing two patients on Pitocin drip each. Manager S707 indicated that if the nurses needed help the OB management team will assist them. The manager stated they follow AWHONN schedule standards for the Obstetric Units.</p> <p>On 09/24/2019, at approximately 1:50 pm, Nurse #S708 and Nurse #S710 were interviewed</p>	A 043		

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A 043	<p>Continued From page 74</p> <p>concerning the Pitocin drip. They stated that they are aware that each nurse should manage one patient on Pitocin drip and not two. The Nurses indicated that it gets busy very fast and they usually finished managing more than one patient on Pitocin. When the two nurses were asked if the patient continue on the Pitocin drip or if any have been discontinued, they both stated, "It continue".</p> <p>Labor induction as the end of pregnancy nears, the cervix normally becomes soft (ripe) and begins to open (dilate) and thin (efface), preparing for labor and delivery. When labor does not naturally start on its own and vaginal delivery needs to happen soon, labor may be started artificially (induced). Even though inducing labor is a fairly common practice, childbirth educators encourage women to learn about it and about the medicine for stimulating a stalled labor (augmentation) so that the women can help decide what is right for them. When labor is induced for medical reasons, it is usually because it's safer for the woman to have the baby now rather than risk further problems from staying pregnant. The labor may be induced for one of the following reasons:</p> <ul style="list-style-type: none"> <li>- pregnancy has gone 1 to 2 weeks past the estimated due date,</li> <li>- a condition (such as high blood pressure, placenta abruptio, infection, lung disease, preeclampsia, or diabetes) that may threaten a woman's health or the health of the baby if the pregnancy continues,</li> <li>- the water (amniotic sac) has broken but active</li> </ul>	A 043			

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A 043	<p>Continued From page 75</p> <p>labor contractions have not started,</p> <p>- the baby has a condition that needs treatment, and the risks of vaginal delivery are low. Induction and vaginal delivery are not attempted if the baby may be harmed or is in immediate danger. In such cases, a cesarean delivery (C-section) is usually done.(Author: Healthwise Staff Medical Review:Kathleen Romito MD - Family Medicine &amp; Adam Husney MD - Family Medicine &amp; Kirtly Jones MD - Obstetrics and Gynecology).</p> <p>On 10/25/2019, Hospital 2 CNO was interviewed. He indicated that the hospital adopted AWHONN standards for schedule needs in the OB Units.</p> <p>Record review of the AWHONN 2010 Schedule Needs standards provided by Hospital 2 CNO indicated:</p> <p>"Patient assignment for women receiving Pitocin (Oxytocin) for labor induction or augmentation should be 1 nurse to 1 woman to be able to assess maternal and fetal status every 15 minutes, consistent with safe care."</p> <p>"If a nurse cannot clinically evaluate the effect of the medication at least every 15 minutes, the Oxytocin infusion should be discontinued until that level of maternal and fetal care can be provided."</p> <p>Hospital 2 CNO stated that he knew the hospital adopted the AWHONN Schedule Needs standards as the hospital policy for the Obstetric and Neonatal Units.</p>	A 043		

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A 043	Continued From page 76  On 09/23/2019, at 10:30 am, Administrative Nursing Director for the Obstetric Unit was interviewed. The Director stated that they follow the AWHONN Guidelines for Professional Registered Nurse Staffing for the Perinatal Unit. According to the Director the hospital administration adopted these guidelines as Policy.  Record review of the AWHONN guidelines for the Obstetric Triage Care Unit 2010 indicated that in the Triage Care Unit the initial process (10 to 20 minutes) requires 1 nurse for 1 woman. The ratio changes to 1 nurse to 2-3 women as maternal-fetal status is determined to be stable.  Record review of an incident report written on 8/13/2019 for Patient #S431. The record indicated that the patient was admitted to the Labor and Delivery Unit at 11:30 am. The patient was diagnosed with a severe range of blood pressures. The patient had doctor's orders to initiate a Magnesium Sulfate bolus at 2:30 pm to prevent seizures in the obstetric patient due to hypertension (pre-eclampsia).  The nurse placed several calls to management because there were no pumps in the unit. At 12:30 pm, the nurse located a pump from another unit but it was malfunctioning. According to the nurse, it is a critical medication in the treatment of pre-eclampsia and needed to be administered as soon as possible. The nurse also needed a channel because the one available was	A 043			

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A 043	<p>Continued From page 77</p> <p>malfunctioning. This equipment unavailability and malfunction caused a delay in treatment. The medication was administered at 3:46 pm.</p> <p>An investigation was conducted by the facility. The investigator on this incident concluded that there was no harm to the patient, just a delay in treatment. The investigator failed to recognize that a delay of administration of such critical medication can cause a seizure activity in the obstetric patient and can cause harm to the unborn child.</p> <p>On 9/23/2019, an obstetric Patient #430 was admitted to the Labor and Delivery Unit at 10:56 pm. The patient was admitted for a Pitocin induction due to a non-reassurance fetal monitor strip. According to nursing documentation, the Pitocin Induction was not able to be started at 10:56 pm because there were no intravenous infusion pumps available. The patient's Pitocin Induction was not started until 9:30 am on 9/24/2019. This delay in treatment could have resulted in a negative outcome to the fetus due to fetal distress.</p> <p>On 9/25/2019 at 2:00 pm, the Hospital 2 CNO #S331 was interviewed. He stated that the hospital had a big problem with getting intravenous pumps.</p> <p>On the afternoon of 9-25-2019, an interview was conducted at Hospital #2 with the Chief Nursing Officer (CNO). During review of nursing policies and the nurse staffing plan, it was found that not</p>	A 043			

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A 043	<p>Continued From page 78</p> <p>all policies were adopted by the Governing Body. It was found that the Nurse Staffing Plan had not been sent through through Governing Body for review and approval. Since nurse staffing directly affected quality of patient care, the CNO was asked why policies and the nurse staffing plan had not been put through the Governing Body for review and approval. The CNO stated, "I've been a CNO for 10 years. There's not a hospital in Texas that sends their nurse staffing plan to the Governing Body." When asked about putting policies and the professional nursing standards that were being used to direct nursing staff on how to provide direct patient care before the Governing Body for review and approval, the CNO explained that only policies that affected how other departments or medical staff operated were put through other committees for approval. Otherwise, the polices and standards that only affected nursing were adopted by the nursing department and did not require further review and approval.</p> <p>Later in the afternoon of 9-25-2019, a conference call was conducted with Chief Nursing Executive on the telephone line. When asked about putting the nurse staffing plan through Governing Body for review and approval since it affected quality of patient care she stated, "Our medical partners do not know nursing standards so they wouldn't understand the staffing guidelines we use to develop the plan."</p> <p>Review of Texas Health and Safety Code; Title 4. Health Facilities; Subtitle B. Licensing of Health Facilities; Chapter 257. Nurse Staffing; Sec. 257.003. NURSE STAFFING POLICY AND</p>	A 043			

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A 043	<p>Continued From page 79 PLAN; included:</p> <p>"(a) The governing body of a hospital shall adopt, implement, and enforce a written nurse staffing policy to ensure that an adequate number and skill mix of nurses are available to meet the level of patient care needed."</p> <p>Review of Sec. 257.004. NURSE STAFFING COMMITTEE; included:</p> <p>"(g) The committee shall:</p> <p>(1) develop and recommend to the hospital's governing body a nurse staffing plan that meets the requirements of Section 257.003;</p> <p>...</p> <p>(5) submit to the hospital's governing body at least semiannually, a report on nurse staffing and patient care outcomes, including the committee's evaluation of the effectiveness of the official nurse services staffing plan and aggregate variations between the staffing plan and actual staffing."</p> <p>Review of Board of Trustees (Governing Body) Meeting Agenda for December 6, 2018, and June 27, 2019, with attachments showed that "Review and Discussion Regarding the Harris Health System Staffing Advisory Committee's Semi-Annual Evaluation of the Nurse Staffing Plan and Aggregate Staffing Variance" was included. The attachments did not include aggregate variations between the staffing plan and actual staffing throughout the period being evaluated. Review of the Minutes of the Nurse Staffing Advisory Committee meeting minutes for meeting between December 2018 through July</p>	A 043			



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A 043	<p>Continued From page 80</p> <p>2019 did not include aggregate variations between the staffing plan and actual staffing.</p> <p>Review of document titled "Harris Health System Professional Nursing Organization Bylaws" was made as follows:</p> <p>"Article 1</p> <p>Professional Nursing at Harris Health System</p> <p>Section 1.1 - Purpose of the Bylaws</p> <p>These bylaws provide for the governance of the Harris Health System professional nursing staff, a framework for its operation, and are reflective of a collaborative process. These bylaws describe the professional nursing staff and their roles and responsibilities within a shared governance model. The professional nursing staff is a component of the Harris Health System and not a separate legal entity or organization."</p> <p>No evidence was found that the Governing Body had approved the bylaws along with approval of the Nursing Department to structure its department using a shared governance model. Review of the bylaws, Article 5, Adoption and Revision of Bylaws did not include a process for the Governing Body to approve the bylaws as the governance of the Harris Health System professional nursing staff and as a framework for its operation</p> <p>Record review of the Medical Staff Bylaws, dated 2018 stated the term "Qualified Medical Personnel" or "QMP" shall mean individuals that are determined qualified by the Medical Staff to</p>	A 043			

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A 043	<p>Continued From page 81</p> <p>provide appropriate medical screening and who may be able to provide necessary stabilizing treatment in the event of an emergency.</p> <p>Record review of the initial privileges dated and signed on 07/16/2019 for Nurse Practitioner staff (ID # S729) and on 03/28/18 for Physician Assistant staff (ID# S730) assigned to the ED. There was no assignment of MSE privileges noted in the scope of practice.</p> <p>Interview on 09/26/2019 at 4:30 p.m. with Quality Management (staff ID # S728) was asked about the MSE appointment for providers in the ED. She stated "its not there and we are working on it. Hospital2</p> <p>Findings:</p> <p>Review of the list of employees that was presented when asked for a list of individuals that could perform a medical screening exam, a list of approximately 123 employees was submitted. The title of the list stated "Active Faculty as of 9/20/2019 4:10 PM. On this list were MD, NP, PA, PA-C. A random selection of these employees from this list were made and credentialing files were reviewed.</p> <p>In there interim, an interview with Personnel #S309 on 9/24/2019 at approximately 11:45 AM in the Conference Room on the Fifth Floor, Personnel #309 was asked about the Qualified Medical Professional (QMP) that perform the medical screening examination in the emergency center. Personnel #S309 stated that they use Physician Assistants (PA's), Nurse Practitioners (NP), attendings, and fellows. Personnel #308 was asked if each one of the names on the list</p>	A 043			

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A 043	Continued From page 82 had been designated by the Governing Body to perform Medical Screening Examination in the emergency center. Personnel #S309 stated "No" not formally designated.  The EMTALA definition for who may perform a medical screening examination documents: "The MSE must be conducted by an individual(s) who is determined qualified by hospital by-laws or rules and regulations and who meets the requirements of 482.55 concerning emergency services personnel and direction. The designation of the qualified medical personnel (QMP) should be set forth in a document approved by the governing body of the hospital...It is not acceptable for the hospital to allow informal personnel appointments that could frequently change." 42 CFR 489.24 (a). Non-physician staff who performs MSE for individuals presenting for examination of a medical condition must be designated by the Governing Body.	A 043			
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:	A 115			

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A 115	<p>Continued From page 83</p> <p>(A) Based on observation, interview, and record review, the facility's direct care staff failed to follow the manufacturer's direction for use when testing water used for hemodialysis of patients for total chlorine in 1 of 1 observation. Failure to test water using the correct volume of water recommended by the manufacturer for the water treatment system has the potential of giving an incorrect result as to the presence of chlorine in the water which can potentially harm all patients receiving hemodialysis treatment in the facility.</p> <p>(B) The facility failed to ensure hemodialysis machines in use in the facility for hemodialysis treatment of patients' dialysate solution had electrolyte analysis done by a laboratory when putting hemodialysis machine in service in 15 of 18 hemodialysis machines observed. Hemodialysis machine #s 5155, 5156, 5157, 5158, 5159, 5160, 5161, 5162, 5163, 5164, 5165, 5166, 5167, 5169, and 5170. Failed to conduct conductivity and PH of the dialysate solution at the of site of treatment.</p> <p>Cross Reference A144</p> <p>(C) The facility failed to provide evidence that 26 of 26 patients reviewed specifically for patient rights at facility #2 were informed of their rights in advance of furnishing patient care and prior to discharge affecting Patient's #s 135, 351, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, and 397.</p> <p>Specifically, patients' medical records did not contain a signed copy of their patient rights or</p>	A 115			

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A 115	<p>Continued From page 84</p> <p>evidence they were provided and explained their patient rights during the registration process in accordance with the facility's policy.</p> <p>Cross Reference A117</p> <p>(D) Hospital #1 failed to follow the process for resolution of patient grievance when the complaints required further investigation, were not resolved at the time of the complaints, and/or the patient requested a response from the hospital.</p> <p>Cross reference A118</p> <p>(E) The facility failed to ensure patients, or their legally authorized representatives (as allowed by State Law) the right to make informed decisions regarding their care and treatment. Specifically Patient's #379, #382, #391, #392, and #393 reviewed at Facility #2 were administered/injected with psychoactive medications that were not deemed a psychiatric emergency without providing informed written consent prior to the administration of the medications in accordance with the facility's policy for use of psychoactive medications.</p> <p>Cross reference A131</p> <p>(F) (a) The facility failed to take timely action to ensure patient care needs were not neglected (a form of abuse) at Hospital #2 after repeated reports of patients not receiving vital medications on time due to the Labor and Delivery Unit not having access to the required equipment for</p>	A 115			

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A 115	<p>Continued From page 85</p> <p>administration of medication. The facility was aware that Intravenous (IV) infusion equipment was not readily available to staff at times and neglected to investigate the process to identify problems associated with the timely distribution of IV infusion equipment. The facility neglected to take immediate actions to ensure vital IV infusion equipment was available for patient care. This failure to take action repeatedly left patients with delays in receiving vital medication.</p> <p>(b) Failed to ensure patient rights to be free from all forms of abuse and neglect by failing to thoroughly investigate and/or respond to an allegation of neglect in accordance with their policies and procedures for 1 of 1 patients reviewed (Patient #383) with an allegation of neglect reported on his behalf at facility #2.</p> <p>Cross reference A145</p> <p>(G) The facility failed to ensure restraints were discontinued at the earliest possible time according to the physician orders and facility policy for 1 of 8 Patients (Patient #382) reviewed for restraints at facility #2. Specifically, Patient #382 remained in 4 point restraints while nursing documentation indicated he was resting and subdued during assessments on 6/7/19 at 00:15 until released from restraints at 08:06 AM (over 8 hours).</p> <p>Cross reference A174</p> <p>(H) The facility failed to have a physician or other licensed independent practitioner (LIP) see the patient face-to-face within 1-hour after the</p>	A 115			

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A 115	Continued From page 86 initiation of a restraint used for the management of violent or self-destructive behaviors for 4 of 8 patients (Patient's #379, #391, #394, and #395) reviewed for restraints at facility #2. Specifically,  (a) Patients were being administered psychotropic medications used to control violent behaviors and were not seen face-to-face within 1-hour after the administration of the medications to evaluate the effect of the intervention, and  (b.) Patients had 4-point physical restraints implemented to control violent behaviors and were not seen face-to-face within 1-hour after the initiation of the 4-point restraints.	A 115			
A 117	Cross Reference A 178 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 upon observation, record review, and interview, the facility failed to provide evidence that 26 of 26 patients reviewed specifically for patient rights at facility #2 were informed of their patient rights in advance of furnishing patient care and prior to discharge affecting Patient's #s 135, 351, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, and 397. Specifically, patients medical records did not contain a signed copy of their patient rights or evidence they were	A 117			

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A 117	<p>Continued From page 87</p> <p>provided and explained their patient rights during the registration process in accordance with the facility's policy.</p> <p>Findings:</p> <p>Review of the facility's policy titled Patient Rights and Responsibilities, last reviewed 8/30/19, revealed the following in part: Copies of the facility's Rights and Responsibilities will be made available to patients or the patient's Legal Representative in the following ways including, "a. Provided and explained to all inpatients and outpatients during the registration process by [the facility's] Patient Access Management staff with a signed and written acknowledgment obtained from the patient or the patient's Legal Representative on [the facility's] Form No. 283301."</p> <p>Review of the Form No. 283301 titled, "Consents, Agreements, Authorizations, Acknowledgements and Irrevocable Assignments," last revised 8/19, documented the following for patient rights: "VII. Acknowledgement of receipt of patient Rights and Responsibilities" indicating "I have been informed and received a copy of [the facility's] Patient's Rights and Responsibilities." The patients signature is documented on page 2 for declaration that the patient read the document and understands the contents regarding the above initialed consents, agreements, authorizations, acknowledgments, and irrevocable assignments.</p> <p>Review of the facility's Patient Rights and Responsibilities Form #284585 dated 12/17 indicated the patient or personal representative had the right to get information about the facility's</p>	A 117			



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A 117	<p>Continued From page 88</p> <p>patient rights when "you are admitted to the hospital or in advance of [the facility] providing or stopping the provision of care to you."</p> <p>Observation conducted in Facility #2 on 9/17/19 at 12:35 PM, of the Emergency Center (EC), Room 33 revealed, Patient Access/Registration Clerk #S353 was completing the admission/registration process for Patient #377. There was not a discussion or explanation regarding Patient's rights. Staff #S353 verifies Patient #377's date of birth, social security number, address, and Gold card (insurance funding). Staff #S353 tells Patient #377, "I just need 2 forms signed today." Patient #377 asks, "What 2 forms?" Staff #S353 responds, "Consent to get treatment by the Doctor today and to verify insurance coverage." Patient #377 signs the electronic forms on the computer and then Staff #S353 offers her a welcome packet.</p> <p>Review of the welcome packet revealed the patient rights and responsibilities was not part of the welcome packet. Review of the 2 forms signed in Patient #377's record revealed the above Form 283301 and the Insurance Verification Form No. 283825.</p> <p>Observation conducted in Facility #2 on 9/24/19 at 2:13 PM, of Patient Access/Registration Clerk #S679 who was registering Patient #396 in the waiting area of the EC revealed, Staff #S679 asked Patient #396 to verify her address and demographics. Staff #S679 tells Patient #396 that he needed her signatures for "some forms; consent form" [Consents, Agreements, Authorizations, Acknowledgements and Irrevocable Assignments], "MAP for any type of prescription meds and PHI" [Medication</p>	A 117			

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A 117	<p>Continued From page 89</p> <p>Assistance Program Consent and Authorization for to Use and Disclose of Protected Health Information], and Insurance Verification." Patient #396 signs the electronic key pad for these specified forms. There was no discussion or explanation regarding Patient's rights. Staff #S679 then hands Patient #396 a welcome packet of forms.</p> <p>Review of the welcome packet of forms revealed the patient rights and responsibilities was not part of the welcome packet.</p> <p>Further observation on 9/24/19 at 2:45 PM consisted of another Patient Access/Registration Clerk #S 681 registering Patient #397 in the EC who was being admitted for observation status and surgery.</p> <p>Staff #S681 verifies Patient #397's insurance coverage and provided the Important Message from Medicare. There was no discussion or explanation regarding Patient's rights for this patient that was being admitted for observation status and anticipation of surgery during the registration process.</p> <p>Interview on 9/17/19 at 12:17 PM, with Patient Access Staff #S353 stated that during the registration process for patients she would verify the Patient's demographic information, insurance information, and have them sign the consents forms which included the insurance verification, medication assistance, PHI Health exchange, and consent for treatment. Staff #S353 then stated they would present the patient with a "welcome packet." After review of the welcome packet of</p>	A 117		

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A 117	<p>Continued From page 90</p> <p>forms revealed the patient rights and responsibilities was not part of the packet given to the patient. Further interview with Staff#S353 revealed no indication that she would review or explain to patients their rights or have them sign regarding their patient rights.</p> <p>Interview on 9/24/19 at 2:00 PM, with Patient Access Staff #S679 stated when asked that patient's rights were reviewed with patients only "if they are admitted" to the hospital. Staff #S679 stated that if the patient is admitted, then the patient access/registration staff will follow up with the patient to review patient rights with the patient and give them a "pass code" for visitors.</p> <p>Interview on 9/24/19 at 2:30 PM, with the Manager of Patient Access (PA) Staff #S 680 stated that patients are given a copy of the patient's rights and responsibilities form in their welcome packet.</p> <p>Surveyor informed Staff #S680 after review of the welcome packets given to Patient's #377 and #396 during the registration process did not include the patient rights and responsibilities form.</p> <p>Staff # S680 responded that she was currently making copies of the patient rights form "now and putting it in the packets now." Staff #S680 stated, "patients sign on the consent Form No. 283301 [Consents, Agreements, Authorizations, Acknowledgements and Irrevocable Assignments] that they have been informed of their rights. Staff #S680 confirmed patients do</p>	A 117			

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A 117	Continued From page 91 not sign an actual copy of the patient rights and responsibilities form and confirmed there is nothing specific that included documentation that the PA staff explained to all patients (inpatients and outpatients) during the registration process their patient rights except the acknowledgment obtained from the patient or the patient's Legal Representative on Form No. 283301.  Interview on 9/24/19 at 2:50 PM, Patient Access Staff #S681 was asked about patient rights and specifically when the patient was explained or informed of their patient rights. Staff #S681 indicated patient rights were "done in the consent form" [Form No. 283301] when they are initially registered.  Record review of 26 patients specifically reviewed for patient rights (Patients # 135, 351, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, and 397) which included a sample of medical records including inpatient, revealed no evidence or documentation that Patients signed a copy of their patient rights, were given a copy of the Patient Rights, or were informed of their Patient's Rights either orally and/or in writing. The medical records contained the above Form No. 283301 titled, Consents, Agreements, Authorizations, Acknowledgements, and Irrevocable Assignments signed by the patient and/or representative.	A 117			
A 118	PATIENT RIGHTS: GRIEVANCES CFR(s): 482.13(a)(2)  The hospital must establish a process for prompt	A 118			

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A 118	<p>Continued From page 92</p> <p>resolution of patient grievances and must inform each patient whom to contact to file a grievance.</p> <p>This STANDARD is not met as evidenced by: Based on interviews and record reviews, Hospital #1 failed to follow the process for resolution of patient grievance when the complaints required further investigation, were not resolved at the time of the complaints, and/or the patient requested a response from the hospital in 2 of 2 Patient's grievances filed.</p> <p>Findings:</p> <p>Review of complaint log for the most recent 3 months revealed the following:</p> <ul style="list-style-type: none"> <li>- Patient #349 complaint on "Loss" reported on 8/27/19 and closed on 9/10/19.</li> <li>- Patient #348 complaint on "Care/Treatment" reported on 7/1/19 and closed on 7/16/19.</li> </ul> <p>Review of "Current Summary" report with eIRS# 153906 reflected Patient #349 contacted Patient Relations on 8/27/19 regarding his loss belongings (beige shoes with leather bottom, jeans, purple shirt, hat, bill fold with ID, debit/credit cards, and grey sweater) while visiting the Emergency Center on 8/24/19.</p> <p>Follow up memo from Staff S601 on 8/28/19 at 11:36 a.m. to other personnel on the subject of "lost belongings" reflected (Patient #349) " ... wants to obtain information regarding the steps that were taken to look into his missing items." After internal investigations that involved multiple personnel, interviews, and camera footage</p>	A 118			

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A 118	<p>Continued From page 93</p> <p>reviews, a telephone follow-up was made to Patient #349 on 9/10/19 and the case was "closed."</p> <p>Review of "Current Summary" report reflected Patient #348 contacted Patient Relations on 7/1/19 regarding complaints related to her care and treatment during "06/11/2019 IR (radiology) appointment" (multiple attempts initiating IV, pain, swollen hand). After internal investigations that involved other personnel, a telephone follow-up was made to Patient #348 on 7/16/19 and the case was "closed."</p> <p>In an interview on 9/23/19 at 2:25 p.m., Staff# S531 examined these two complaint files and confirmed they should have been processed as grievances.</p> <p>Review of policy titled Patient Complaints and Grievances, policy # 4200, with effective date of 03/30/06, reflected the following under Policy Elaborations: I. Definitions:</p> <ul style="list-style-type: none"> <li>- "A. Complaint: A request or concern that is communicated verbally by a complainant regarding patient care or services that is resolved at the time of the Complaint by staff present."</li> <li>- "C. Grievance: A formal or informal written or verbal Complaint that is made to the hospital by a patient, or the patient's representative, regarding ... patient's care (when the Complaint is not resolved at the time of the Complaint by staff present) ... when the patient requests a response from the hospital, the Complaint is considered a</li> </ul>	A 118			

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A 118	Continued From page 94 Grievance."	A 118			
A 131	<p><b>PATIENT RIGHTS: INFORMED CONSENT</b> CFR(s): 482.13(b)(2)</p> <p>The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.</p> <p>The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.</p> <p>This STANDARD is not met as evidenced by: Based on records reviewed and interviews, the facility failed to ensure patients or their legally authorized representatives (as allowed by State Law) the right to make informed decisions regarding their care and treatment for 5 of 5 patient records reviewed for psychoactive medications that were not deemed a psychiatric emergency.</p> <p>Specifically, Patients #s 379, #382, #391, #392, and #393 reviewed at Hospital (#2) were administered/injected with psychoactive medications that were not deemed a psychiatric emergency and without providing informed written consent prior to the administration of the medications in accordance with the facility's policy for use of psychoactive medications.</p> <p>The facility failed to ensure that Disclosure and Consents for medical and surgical procedures are completed accordingly in 1 of 1 record</p>	A 131			

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A 131	<p>Continued From page 95 reviewed.</p> <p>Findings:</p> <p>Review of the facility's policy titled "Consent to Treatment with Psychoactive Medication" effective 03/11, no revisions or reviews, indicated the following in part:</p> <p>B. Before administering psychoactive medication to any patient, the attending physician or designee will explain to the patient and/or the patient legally authorized, the following in simple non-technical language in the person's primary language, if possible.</p> <p>10. A written Consent for Treatment with Psychoactive Medications (HCHD) Form 281464 must be completed for each psychoactive medication administered.</p> <p>D. Psychoactive medication will not be administered to psychiatric patient under voluntary, emergency, or Order of Protective Custody (OPC) provision without informed consent except in the case of an emergency situation.</p> <p>Review of the facility's Form #281464 titled "Consent to Treatment with Psychoactive Medication" last revised 8/19, revealed it contained the specific requirements to obtain written informed consent in accordance with the policy.</p> <p>Patient #379</p>	A 131			



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A 131	<p>Continued From page 96</p> <p>Physician Order (PO) 7/5/19 at 20:12, Ativan 2 milligrams (mg) stat Intravenous (IV) push once.</p> <p>Medication Administration Record (MAR) indicated administered at 20:05</p> <p>PO 7/6/19 at 17:35, Ativan 2mg stat IV push once. MAR indicated administered at 17:00</p> <p>PO 7/6/19 at 20:13, Ativan 2mg stat IV push once. MAR indicated administered at 20:30</p> <p>Review of Patient #379's medical records revealed there was not an informed written consent prior to the administration of Ativan.</p> <p>Patient #382</p> <p>PO 6/6/19 at 19:32, Haloperidol lactate (Haldol) injection 1mg once. MAR - administered at 19:52</p> <p>PO 6/7/19 at 08:47 AM, Risperidone 1mg tablet 2 times daily. MAR - administered on 6/7/19 at 08:45.</p> <p>PO 6/7/19 at 08:50 AM, Risperidone (Risperdal) 1mg oral tablet every 6 hours PRN for agitation. Psychiatric emergency - No.</p> <p>PO 6/7/19 at 11:11 AM, Lorazepam 2mg/ml injection, 2mg Intramuscular (IM) every 6 hours PRN for agitation, 2nd line, only if 1g risperidone is not sufficient. Psychiatric emergency - No.</p> <p>PO 6/7/19 at 11:11 AM, Haloperidol lactate (Haldol) injection 5mg intramuscular every 6 hours PRN for agitation, 2nd line, only if 1g risperidone is not sufficient, not to exceed 20mg</p>	A 131		

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A 131	<p>Continued From page 97 total in a day.</p> <p>Review of Patient #382's medical records revealed there was not an informed written consent prior to the administration of Ativan (Lorazepam), Haldol, and Risperidone.</p> <p>Patient #391</p> <p>PO 8/28/19 at 04:30, Haldol 5mg IM once stat. MAR- administered at 04:31, psychiatric emergency - No.</p> <p>During an interview on 9/24/19 at 11:30 AM, with the Quality Coordinator Staff (#S677) during review of Patient #391's medical records indicated there was not a reason stated on the order for Haldol. There also was not an identified mental illness indicated in the diagnosis area of his Provider notes. Staff #S677 confirmed Patient #391's EMR did not have written informed consent prior to the administration of Haldol.</p> <p>Patient #393</p> <p>PO 7/4/19 at 12:00, Haldol 1 mg IM in 2C (Med surg) every 8 hours PRN for agitation. Psychiatric Emergency - No. MAR- administered once 7/4/19 at 19:58</p> <p>PO 7/3/19 at 03:47, Ativan 2mg IV push once. MAR- administered at 03:47. Psychiatric emergency - No. No reason indicated on physician order.</p> <p>Review of Patient #393's medical records revealed there was not an informed written</p>	A 131			

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A 131	<p>Continued From page 98</p> <p>consent prior to the administration of Haldol and Ativan.</p> <p>Patient #394</p> <p>PO 9/4/19 at 07:46, Haldol 2.5mg IV. Psychiatric emergency - No. MAR- administered 07:54</p> <p>PO 9/4/19 at 11:06, Zyprexa 5mg 2 times daily orally. Psychiatric emergency - No. The order did not have a diagnosis or reason for the order. MAR revealed Zyprexa administered 9/4/19 at 11:59 and at 19:55.</p> <p>Review of Patient #394's medical records revealed there was not an informed written consent prior to the administration of Haldol and Zyprexa.</p> <p>Interview with Staff #S671 on 9/26/19 at 09:50 AM, stated, the policy titled "Consent to Treatment with Psychoactive Medication" was "outdated." Staff #S671 further confirmed the facility was not obtaining informed written consent from the patient or the patient's LAR prior to administration of Psychoactive Medications; using Form 281464 in accordance with the facility's policy unless the patient was being treated at the Psychiatric inpatient unit of Facility #1.</p> <p>Hospital #2</p> <p>Patient #436's records were reviewed and two of her consents did not have witness signatures, name, title, nor ID numbers. One consent was issued for the placement of a peripheral intravenous catheter and the other consent was</p>	A 131			

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A 131	Continued From page 99 for a blood transfusion.  Patient #436 was interviewed on the afternoon of 09/24/2019, and she explained that she did not remember anyone else signing the document. In addition, Patient #436 stated that she was not given a copy of the consent.  It was noted that the Patient is a Spanish speaker and used an interpreter at the time of signing her consent yet she was not given a copy of the document in Spanish to read or keep.	A 131			
A 132	PATIENT RIGHTS: INFORMED DECISION CFR(s): 482.13(b)(3)  The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).  This STANDARD is not met as evidenced by: Based on observations, interviews, and record reviews, the facility's registration staff failed to ask about patient's current advance directives status in accordance with their policy, and/or provide the patients with accurate information concerning their rights on formulating advance directives for 3 of 3 patients (Patient's # 377, #396, and #397) reviewed specifically for advance directives at Facility #2.  Findings:	A 132			

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NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 132	<p>Continued From page 100 Patient #377</p> <p>Observation conducted in Hospital #2 on 9/17/19 at 12:35 PM, in Room 33 of the Emergency Center (EC) revealed, the Patient Access Management (PAM) staff #S353 was completing the admission/registration process for Patient #377. There was no discussion or explanation regarding Patient's rights. Staff #S 353 did not ask Patient #377 if she had advance directives or if she would like information on how to formulate advance directives. Staff #S353 verifies Patient #377's date of birth, social security number, address, and Gold card (insurance funding). Staff # S353 tells Patient #377, "I just need 2 forms signed today." Patient #377 asks, "What 2 forms?" Staff #S353 responds, "Consent to get treatment by the Doctor today and to verify insurance coverage." Patient #377 signs the electronic forms on the computer and then Staff #S353 offers her a welcome packet.</p> <p>Review of the welcome packet revealed the patient rights and responsibilities were not part of the welcome packet. The welcome packet also did not have information regarding Advance Directives (Form # 283322).</p> <p>Review of the 2 forms signed in Patient #377's record revealed the above Form 283301, and the Insurance Verification Form No. 283825.</p> <p>Patient #396</p> <p>Observation on 9/24/19 at 2:13 PM, of PAM staff #S679 who was registering Patient #396 in the waiting area of the EC (emergency center) revealed, Staff #S679 asked Patient #396 to</p>	A 132			

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A 132	<p>Continued From page 101</p> <p>verify her address and demographics. Staff #S679 tells Patient #396 that he needed her signatures for "some forms, consent form" [Consents, Agreements, Authorizations, Acknowledgements, and Irrevocable Assignments], "MAP for any type of prescription meds and PHI" [Medication Assistance Program Consent and Authorization for to Use and Disclose of Protected Health Information], and Insurance Verification. Patient #396 signs the electronic key pad for these specified forms. There was no discussion or explanation regarding Patient's rights. Staff #S679 did not ask Patient #396 if she had advance directives or if she would like information on how to formulate advance directives. Staff #S679 then hands Patient #396 a welcome packet of forms.</p> <p>Review of the welcome packet of forms revealed the patient rights and responsibilities were not part of the welcome packet. The welcome packet also did not have information regarding Advance Directives (Form #283322).</p> <p>Further observation on 9/24/19 at 2:45 PM consisted of another PAM staff #S681 registering Patient #397 in the EC who was being admitted for observation status and surgery.</p> <p>Patient #397</p> <p>Staff #S681 verifies Patient #397's insurance coverage and provided the Important message from Medicare. There was no discussion or explanation regarding Patient's rights for this patient that was being admitted for observation status and anticipation of surgery during the registration process.</p>	A 132			

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A 132	<p>Continued From page 102</p> <p>Staff #S681 did not ask Patient #397 if she had advance directives or if she would like information on how to formulate advance directives.</p> <p>Interview on 9/17/19 at 12:17 PM, with Patient Access Staff #S353 stated that during the registration process for patients she would verify the Patient's demographic information, insurance information, and have them sign the consent forms, which included the insurance verification, medication assistance, PHI Health exchange, and consent for treatment. Staff # S353 then stated, they would present the patient with a "welcome packet."</p> <p>After review of the welcome packet of forms, revealed the patient rights and responsibilities were not part of the packet given to the patient or the information regarding Advance Directives (Form #283322).</p> <p>Further interview with Staff #S353 revealed no indication that she would review or explain to patients their rights or have them sign regarding their patient rights. Staff #S353 stated that she was supposed to ask patients if they had advance directives and/or if the patient wanted information on how to formulate advance directives.</p> <p>Interview on 9/24/19 at 2:00 PM, with Patient Access Staff #S679 stated when asked if patient's rights were reviewed with patients only, she stated, "if they are admitted" to the hospital. Staff #S679 stated that if the patient is admitted, then the patient access/registration staff will follow up with the patient to review patient rights with the patient and give them a "pass code" for visitors.</p>	A 132			

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A 132	<p>Continued From page 103</p> <p>Further interview at 02:25 PM, with Staff #S679 confirmed he did not ask Patient #396 if she had advance directives because she had been asked before; and staff only have to ask if the patient is a "New Patient."</p> <p>Staff #S679 showed the surveyor Patient #396's electronic record during the interview that already had documentation that Patient #396 did not have an advance directive. Staff #S679 confirmed, he did not provide Patient #396 with information regarding advance directives. Staff #S679 stated, the majority of patients have been at the facility before for care/treatment and their electronic medical record will already have documented from previous visits if they do or do not have advance directives.</p> <p>Interview on 9/24/19 at 2:30 PM, with Staff #S680 stated that patients were supposed to be asked if they have advance directives during the registration process and that patients were given a copy of the patient's rights and responsibilities form in their welcome packet.</p> <p>Surveyor informed Staff #S680 after review of the welcome packets given to Patient's #377 and #396 during the registration process; did not include the patient rights and responsibilities form or the form regarding Advance Directives.</p> <p>Staff #S680 responded that she was currently making copies of the patient rights form "now and putting it in the packets now." Staff #S 680 further stated that the Advance Directive form #283322 is provided to patients if they want more information on formulating advance directives.</p>	A 132			



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A 132	<p>Continued From page 104</p> <p>Staff #S680 indicated, patients sign on consent Form No. 283301 [Consents, Agreements, Authorizations, Acknowledgements, and Irrevocable Assignments] that they have been informed of their rights. Staff # S680 confirmed, patients do not sign an actual copy of the patient rights and responsibilities form and confirmed there is nothing specific that included documentation that the PAM staff explained to all patients (inpatients and outpatients) during the registration process their patient rights except the acknowledgment obtained from the patient or the patient's Legal Representative on Form No. 283301.</p> <p>Staff #S680 also confirmed the Patients did not sign anything during the registration process specifically if they did or did not have advance directives. Staff #S 680 stated that patients' records will have the information if they have Advance Directives already populated in their electronic record from their previous visits.</p> <p>Interview on 9/24/19 at 2:33 PM, with Patient #396 in the EC waiting area following her registration confirmed she had not been asked today if she had advanced directives during registration by PAM staff. Patient #396 further stated the staff "have asked in the past but not this time."</p> <p>Review of the facility's policy titled, Advance Directives, last reviewed 8/29/19, indicated the following, in part;</p> <p>"The facility shall ask all inpatient, emergency room patients, observation status patients, and day surgery patient, or the patient's Legal</p>	A 132			

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A 132	<p>Continued From page 105</p> <p>Representative if the patient has an Advance Directive and shall document the response in the patient's medical record."</p> <p>Further review of the Appendix G, Advance Directive Emergency Center Process Flow indicated Advance Directives would be obtained by PAM staff during the verification of Demographic info while in the waiting area after triage; or during the bedside registration if patient was sent to a treatment room.</p> <p>Review of the facility's Form #283322 dated 12/14 titled Advance Directives, given to patient's upon request of additional information regarding advance directives revealed the patient could obtain forms at: <a href="http://www.dads.state.tx.us/news_info/publications/handbooks/advancedirectives.html">http://www.dads.state.tx.us/news_info/publications/handbooks/advancedirectives.html</a></p> <p>Review of this website provided in the facility's Form #283322 revealed, it was outdated and the current information for advance directives titled, "DIRECTIVE TO PHYSICIANS AND FAMILY OR SURROGATES," Advance Directives Act (see §166.033, Health and Safety Code) dated 12/2015 was at the following website (English): <a href="https://hhs.texas.gov/sites/default/files/documents/laws-regulations/forms/LivingWill/LivingWill.pdf">https://hhs.texas.gov/sites/default/files/documents/laws-regulations/forms/LivingWill/LivingWill.pdf</a> (Spanish): <a href="https://hhs.texas.gov/sites/default/files/documents/laws-regulations/forms/LivingWill/LivingWill-S.pdf">https://hhs.texas.gov/sites/default/files/documents/laws-regulations/forms/LivingWill/LivingWill-S.pdf</a></p> <p>Review of the facility's policy titled Patient Rights and Responsibilities, last reviewed 8/30/19, revealed the following in part:</p>	A 132			

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A 132	Continued From page 106 Attachment A (Form 284585) indicated the Patient's Rights to have an advance directive. The patient or personal representative had the right to receive notice of the facility's policy regarding Advance Directives prior to receiving treatment.	A 132			
A 144	Review of the Form No. 283301 titled, "Consents, Agreements, Authorizations, Acknowledgements, and Irrevocable Assignments, last revised 8/19, revealed this form was signed by the patient during each registered visit to the facility. Further review of this form revealed, there was no information documented specifically as to whether the patient had an advance directive or did not have an advance directive.  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:  (A) The facility's direct care staff failed to follow the manufacturer's direction for use when testing water used for hemodialysis of patients for total chlorine in 1 of 1 observation. Failure to test water using the correct volume of water recommended by the manufacturer for the water treatment system has the potential of giving an incorrect result as to the presence of chlorine in the water which can potentially harm all patients receiving hemodialysis treatment in the facility.	A 144			

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A 144	<p>Continued From page 107</p> <p>(B) The facility failed to ensure hemodialysis machines in use in the facility for hemodialysis treatment of patients' dialysate solution had electrolyte analysis done by a laboratory when putting hemodialysis machine in service in 15 of 18 hemodialysis machines observed. Hemodialysis machine #s 5155, 5156, 5157, 5158, 5159, 5160, 5161, 5162, 5163, 5164, 5165, 5166, 5167, 5169, and 5170. Failed to conduct conductivity and PH of the dialysate solution at the of site of treatment.</p> <p>(C) The facility failed to ensure patients received care in a safe setting as a bathroom call light cord was inaccessible to a patient experiencing a fall. Sharp objects were accessible to patients on psychiatric unit.</p> <p>(D) Failed to ensure patients received care in a safe setting in that 5 patients did not have the facility required allergy band to prevent the administration of contraindicated medications.</p> <p>(E) The nursing staff failed to conduct the assessments and measurements of wounds, per the facility's policy, to determine if current treatments are effective. (Patients #122, 159, 160, 161, and 162). The nursing staff failed to clearly document wound care orders and failed to ensure recommended preventative measures were being followed for patients at risk for skin breakdown and to prevent further breakdown. (Patients #66 and 158).</p> <p>(F) Hospital 1 failed to monitor humidity and failed</p>	A 144			

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A 144	<p>Continued From page 108</p> <p>to ensure end users were notified if temperatures were outside of acceptable ranges for 6 of 6 (station 15 area, Core D area, A Side Holding area, B Side holding area, Pod 7 area, and the CPU area) Emergency Department areas.</p> <p>(G) Laboratory Issues: Hospital (2), failed to follow manufacturer recommended environmental specification for proper instrument testing conditions. The Facility's Emergency Care (EC) staff failed to follow Hospital (2's) policy for Quality Control for Refrigerator, Freezer, and Platelet Incubator.</p> <p>Findings:</p> <p>(A) On 09/19/2019 at 9:30 a.m., Patient Care Technician #S42 and Registered Nurse #S43 were observed in the water treatment room of Hospital (1). Registered Nurse #S43 was observed testing the facility's water used for hemodialysis treatment of patients for total chlorine during the 4-hourly testing.</p> <p>Observation of the facility's water treatment room at that time revealed a direct feed system in place without a holding tank, (CWP 100 series). Observation revealed the Registered Nurse collected 25 ml of product water in the specimen cup.</p> <p>The Surveyor asked the Registered Nurse how much water was in the cup, he responded, "25 mls". The Surveyor and Registered Nurse verified the volume of water in the cup by looking at the gradation on the container. The Surveyor then</p>	A 144			

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A 144	<p>Continued From page 109</p> <p>asked Registered Nurse #S43 how much water was needed to test for total chlorine, he stated " 20 mls."</p> <p>Registered Nurse #S43 then secured testing reagent strip from Hisense ultra 0.1 container and tested the 25 mls of water in the container for total chlorine. The Surveyor then notified Registered Nurse #S43 that he had used 25 mls of water instead of the recommended 20 by the manufacturer.</p> <p>Registered Nurse #S43 stated "I will re-test it". He then proceeded to discard 5 mls of water from the specimen cup which held the 25 mls of water and proceeded to repeat the test using the existing water he had used for initial testing. The Surveyor notified him that the test result would be incorrect since he had already used a reagent strip in the water for the initial test.</p> <p>Review of the manufacture's instruction on Serim Guardian Hisense Ultra 0.1 Test for Total Chlorine, directs user as follows:</p> <p>"Fill the enclosed sample cup with water to be tested. Discard the contents and refill with 20 ml of water. Start the timer and immerse the indicator pad into the water sample. Vigorously swish test strips back and forth for a full thirty seconds. Remove strip and shake off excess water. Immediately compare color of the indicator pad to the color chart. Record the result and discard the test strip according to federal state and local regulation."</p> <p>Review on 09/21/2019 of Registered Nurse</p>	A 144			

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A 144	<p>Continued From page 110</p> <p>#S43's Orientation Skills Assessment Checklist revealed documentation which indicated the most current hemodialysis skills check list on file was dated 01/04/13 - 2/9/13. There was no current skills assessment for competency for hemodialysis/testing for total chlorine in water used for hemodialysis of patients.</p> <p>Review of a Learning and Resource Center Education History Report for Registered Nurse #S43, dated March 2018 - September 2019 revealed no evidence of skills assessment completed on the Registered Nurse.</p> <p>During an interview on 09/20/2019 at 2:00 p.m., with the Vice President of Nursing for the hospital system, she said the facility did not have or implemented a skills assessment for hemodialysis.</p> <p>(B) Electrolyte analysis</p> <p>Review of the Manufacture's recommendation 2008T Manufacture's Operating Manual, P/N 490122 REV U, Page 18 directs users as follows:</p> <p>"The machine must be labeled to indicate the type of concentrate for which it is configured. Check the composition (i.e. Na, Cl, K, Mg, HCO3) and pH of the dialysate solution after the machine is installed or after the machine is modified for different concentrate type. Verify the conductivity and pH of the dialysate solution through independent means before initiating treatment. Independent means could be by using an external conductivity meter, pH meter, pH paper,</p>	A 144		

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A 144	<p>Continued From page 111 or using the machine's independent conductivity test. Improper conductivity or pH could result in Patient injury or death."</p> <p>Observation on 09/16/2019 at 12:30 PM, of the facility's hemodialysis suite, located on the 6th floor of Hospital #1 revealed, there were 18 Fresenius 2008 T hemodialysis machines in place. Hemodialysis machine #s 5163 and 5169 were observed in use by patients.</p> <p>The Surveyor requested documentation from the biomedical technician that verification of the electrolyte in the dialysis solutions were done by a laboratory. The Hemodialysis Unit's Biomedical Technician provided copies of electrolyte analysis completed on three hemodialysis machines #s 5154, 5168, and 5171. The record indicated the electrolyte analysis were completed on all three hemodialysis on 11/08/2018 and reported on 11/10/2018.</p> <p>Review of Asset Detail Report provided by facility's staff revealed the following hemodialysis machines were put in service on the following days:</p> <p>Hemodialysis machine # 5155 was put into service in the hospital on 11/16/2018.</p> <p>Hemodialysis machine # 5157 was put into service in the hospital on 11/16/2018.</p> <p>Hemodialysis machine # 5158 was put into service in the hospital on 11/16/2018.</p>	A 144			



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A 144	Continued From page 112 Hemodialysis machine # 5159 was put into service in the hospital on 11/16/2018.  Hemodialysis machine #5160 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5161 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5162 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5163 was put into service in the hospital on 12/07/2018.  Hemodialysis machine # 5164 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5165 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5166 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5167 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5168 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5169 was put into service in the hospital on 11/16/2018.  Hemodialysis machine # 5170 was put into service in the hospital on 11/16/2018.  Review of the records revealed no documentation that verification of the electrolyte in the dialysis	A 144			

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A 144	<p>Continued From page 113 solutions were done by a laboratory.</p> <p>Interview on 09/16/2019 12:30 PM, with Hospital (1) Biomedical Technician for the dialysis unit revealed, he had done electrolyte analysis on 3 of eighteen hemodialysis machine put in service in 2018.</p> <p>Conductivity PH</p> <p>Patient #193</p> <p>On 09/23/2019 at 9:46 a.m., Patient # (193) was observed in room 6E of the medical intensive care unit of Hospital (1). The Patient was receiving hemodialysis utilizing 2008T hemodialysis machine # 5171. There was a portable Millennium XL reverse osmosis machine in use. The conductivity reading on the panel of the machine was 39.</p> <p>During an interview on 09/23/2019 at 9:47 a.m., with Registered Nurse #S307 revealed, the conductivity and PH of the dialysate solution and safety check of the hemodialysis machine were done by Patient Care Technician #42 on the hemodialysis unit and then the prepared hemodialysis machine and reverse osmosis machines were taken to the medical intensive care unit. She said after this is done then she checks the total chlorine of the water at the patient's bedside.</p> <p>Review of a dialysis machine system check and disinfection log revealed documentation of a conductivity of 14.0 mS/CM. Review of the Registered Nurse dialysis flow sheet revealed documentation of conductivity reading of 13.8.</p>	A 144			

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A 144	<p>Continued From page 114</p> <p>Conducting conductivity and PH of the dialysate solution and safety check of the dialysis machine in a different environment from where it is utilized can give incorrect reading which can harm the patient. The Ph should be verified to check that the right concentrate mixture is being used</p> <p>Review on 09/20/2019 of Registered Nurse (S307) Orientation Skills Assessment checklist revealed documentation which indicated the most current hemodialysis skills check list was dated 05/25/07. Review of the record revealed no evidence of skills assessment completed on the Registered Nurse for hemodialysis</p> <p>3 out of 3 metal carts for the portable RO and dialysis machines observed, had rust and paint peeling off, therefore, not allowing for proper external disinfection.</p> <p>(C) Bathroom Lights</p> <p>A tour of Hospital(1) Unit 3A was conducted the morning of 9/17/19 accompanied by Staff #S62 and S145 and the following was observed:</p> <p>In patient room 3A 1-1, a shared patient room, the call light cord in the patient bathroom was obstructed by a large trash can, which was placed in front of the call light cord, rendering it out of reach and ineffective for a patient experiencing a fall on the floor to summon help in an emergency. There appeared to be no other place for the large trash can in the bathroom; Staff #S148 draped the call light cord over the trash can in an attempt to make the cord accessible, which left the end of the cord too high and still out of reach for a patient on the floor.</p>	A 144			

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A 144	<p>Continued From page 115</p> <p>The above findings were confirmed in an interview with Staff #S62 and S145 during the tour the morning of 9/16/19.</p> <p>Based on record review, observation, and interview, the hospital failed to ensure the rights of 2 of 13 patients (Patient #1 and Patient #228) on Hospital 1's mental health unit.</p> <p>1) Patient #228, a patient with a history of severe sexual abuse, felt hopeless and anxious. She was on staff monitor for impaired insight and judgement. The patient had access to a staple with the potential for use in self-harm</p> <p>The surveyor observed Patient #228 in bed on 09/20/19 at 1415. A two-page document was observed on the shelf next to the patient's bed. The document was stapled together. Staff #3 acknowledged the findings and removed the staple.</p> <p>Patient #228's Initial Psychiatric Evaluation dated 09/18/19 reflected the patient was in a "down/depressed mood," felt hopeless, and had "flashbacks and nightmares pertaining to a situation that took place recently..." Patient #228 had a history of mental, sexual, and physical abuse and was noted with limited insight and judgement. Her initial diagnoses included Depressed Bipolar.</p> <p>Nurse documentation dated 09/20/19 at 0114, reflected Patient #228 felt hopeless and helpless, and her anxiety prevented her from sleeping.</p> <p>Nurse documentation dated 09/20/19 at 1546, reflected the patient was "seclusive to self or</p>	A 144			

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A 144	<p>Continued From page 116 bed...remains on bizarre precaution monitoring..."</p> <p>Physician Discharge Summary dated 09/23/19 at 1540, reflected the patient was a victim of sex trafficking.</p> <p>Record review of the document titled Unit Specific Psychiatric Precautions, undated, defined "bizarre precautions" indicated for patients "with impaired insights and DSM diagnosis of Psychosis."</p> <p>2) Patient #1 had been admitted with moderately severe depression and a history of eight prior suicide attempts. The patient made a self-harm attempt within two days of admission. During the survey, a sharp wire was found on the patient's unit. It was patient accessible and had the potential for patient self-harm. Observations on 09/20/19 at 1420, on the mental health inpatient unit's day room reflected an approximately three-inch two-pronged piece of wire with sharp edges and a small metal ring in front of a book case. Staff #S3 acknowledged the finding at that time.</p> <p>Record review of the unit census dated 09/20/19 reflected Patient #1 was on suicide precautions.</p> <p>Record review of Patient #1's Initial Psychiatric Evaluation dated 09/07/19 at 0758, reflected, the patient had been admitted with suicidal thoughts. The patient's PHQ-9 (Patient Health Questionnaire-9) reflected a total score of 18. The patient's past psychiatric history included "8 prior suicide attempts by various means ... [including] cutting wrists ..." Stanford University (2019) noted a score of 15 to 19 on the PHQ-9 reflected a moderately severe patient depression</p>	A 144			

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A 144	<p>Continued From page 117 (<a href="http://med.stanford.edu/fastlab/research/imapp/mrs/_jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9%20id%20date%2008.03.pdf">http://med.stanford.edu/fastlab/research/imapp/mrs/_jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9%20id%20date%2008.03.pdf</a>).</p> <p>Nursing documentation dated 09/10/19 at 0404, reflected the patient had a self-inflicted superficial cut on his left wrist.</p> <p>Daily Resident Physician Progress Note dated 09/10/19 at 0748, reflected Patient #1 wanted to hurt himself, had suicidal thoughts the night before and heard a voice telling him to hurt himself.</p> <p>(D) Allergy bands</p> <p>A.) Review of the facility provided policy reflected the patient's allergy band was to be placed on the same arm as the identification band, to prevent the administration of medications a patient may be allergic to.</p> <p>Observations on the morning of 9/24/29, on Hospital (1's) inpatient units, revealed the following:</p> <p>6B room 4.1- Patient #225, had an allergy to Ibuprofen, the allergy band was on right wrist and the identification band was on the left wrist.</p> <p>6D room 2.2- Patient #116, had an allergy to Codeine, the allergy band was on the right wrist and the identification band was on the foot.</p> <p>5E room 9.0- Patient #221, had an allergy to Rocephin and Penicillin, the allergy band was on the left wrist and the identification band was on</p>	A 144			

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A 144	<p>Continued From page 118 the right arm.</p> <p>5G room 1.2- Patient #222, had an allergy to Marcaine, the patient did not have an allergy band on.</p> <p>5G room 4.4- Patient #223, had an allergy to Penicillin, the allergy band was on the left wrist and the identification band was on the right wrist.</p> <p>During an interview on the morning of 9/24/19, on the inpatient units, Staff #S303, Director of Nursing confirmed the findings.</p> <p>(E) Wound Care</p> <p>B.) Review of the facility provided policy #431 PRESSURE INJURY PREVENTION AND TREATMENT (dated 09/2018) reflected, "Upon admission, skin assessment shall be completed by nursing and documented in the patient's medical record and reassessed every shift and during transfer of care between health care providers .... E. The pressure injury (ulcer) prevention plan shall include interventions that minimize or eliminate friction and sheer, minimize pressure with off-loading, manage moisture, and maintain adequate nutrition and hydration ... D. Upon identification of a wound, a full wound assessment, including its location, size, and description of the tissue involved, shall be completed ..."</p> <p>PATIENT #66 Hospital (1)</p> <p>Review of Patient #66's medical records revealed a 62-year-old male presented on 7/10/19 to the</p>	A 144		

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A 144	<p>Continued From page 119 facility's emergency department. The admission photos show the sacral skin is intact.</p> <p>Review of the wound care nurse's notes reflected the following:</p> <p>On 7/12/2019 at 12:26 am</p> <p>Perianal: moisture related skin damage. Skin is moist, macerated, and erythematous. Periwound [sic]: clean, moist, intact.</p> <p>Odor: mild.</p> <p>Category 3 - the skin flap is completely absent. Partial thickness skin loss. Wound bed with 100% red tissue. Edges are irregular, open, attached to base. Periwound: C/D/I. No drainage noted. Braden Score: 14 Level of Risk: H.</p> <p>ADDITIONAL RECOMMENDATIONS:</p> <p>1. Turn pt. Q2hr, avoid supine (lying on the back) position/pressure to wound. Turn left or right side. Use foam wedge for optimal off loading. Provide cushion to hips or apply mepilex border dressing.</p> <p>Review of the Wound Care Nurse's assessments of the Sacral wound revealed the following:</p> <p>On 7/18/19 - Wounds are measured by Length X Width X Depth (LxWxD) in centimeters.</p> <p>Sacrum: Pressure injury, DTI (deep tissue injury) Measurement: 6X4X unable to determine Intact skin with non-blanchable deep red, maroon, purple discoloration. Additional Recommendation: Turn pt. Q 2hrs, turn left or</p>	A 144			



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A 144	<p>Continued From page 120</p> <p>right side, and document. Avoid supine position/pressure to wound. Use foam wedge for optimal off loading.</p> <p>On 8/1/19- Sacrum: Unstageable pressure injury. Measurements: 2X5.2X unable to determine. Wound bed obscured by 45% yellow slough, 5% dark red tissue, and 50% dark tan discoloration to skin. Additional Recommendation: Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal off loading.</p> <p>On 8/8/19 - Sacrum: Unstageable pressure injury. Measurements: 2.5X4X unable to determine. Wound bed obscured by 90% white non-viable tissue and 10% dark red tissue. Additional Recommendation: Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal off loading.</p> <p>On 8/11/19 at 7 PM, the nurse's documented an unstageable sacral wound with excoriation. The nursing documentation did not include measurements of the wounds.</p> <p>On 8/12/19 - the wound care nurse assessed the wounds and wrote orders and recommendations to be followed.</p> <p>On 8/23/19 - Sacrum: Unstageable pressure injury. Measurements: 3X3.8X unable to determine. Additional Recommendation: Turn pt. Q 2hrs, turn left or right side and document. Avoid supine position/pressure to wound. Use foam wedge for optimal off loading.</p> <p>On 9/11/19 - Sacrum: unstageable pressure</p>	A 144			

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A 144	<p>Continued From page 121</p> <p>injury. Wound measures 6.0cmLx6.0cmWx2.0cmD. Undermining noted from 9 o'clock to 5 o'clock. Deepest point at 12 o'clock of 1.2cm. Wound base is 98% tan, tenacious nonviable tissue with 2% pale pink tissue. Edges are defined by not attached. Peri wound is denuded and macerated. Dressing that was removed was saturated with serosanguineous drainage. Additional Recommendation: Turn pt. Q 2hrs, Avoid supine position. Use foam wedge for optimal off loading.</p> <p>On 9/13/19 at 11:47 am, the wound care nurse writes an order for dressing changes but does not describe the location or the area to be changed.</p> <p>On 9/19/19 at 11:03 am, the wound care nurse writes an order for dressing changes but does not describe the location or the area to be changed.</p> <p>Review of Patient #66's turning and repositioning documentation revealed the following:</p> <p>7/12/19 at 2 am - Supine, 7 am- Supine, 11 am- Supine, from PM to 10 PM - no turning was documented.</p> <p>7/13/19 at 8 am - Supine, 6 PM- Supine, 10 PM- Supine</p> <p>7/14/19 at 2 am - Supine, from 6 PM to 6 am- no documented turning.</p> <p>7/15/19 at 6 PM - Supine, 12 am- Supine, 4 am- Supine</p> <p>7/17/19 at 8 am - Supine, 12 PM- Supine, 4 PM, no documented turning.</p>	A 144			

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A 144	Continued From page 122  7/18/19 at 6 am till 7/20/19, the patient was no documented turned, Veniflex, do not turn.  7/21/19 at 6 PM - Supine, 8 PM- Supine  7/22/19 at 8 PM - Supine  7/23/19 at 8 PM - Supine, 2 am- Supine  7/24/19 at 9 am -Supine, from 10 PM to 7 am- no documented turning  7/26/19 at 2 PM - Supine, from 10 PM to 7/27/19 at 6 am- Supine  7/27/19 at 12 PM - Supine  7/29/19 at 10 PM - Supine  7/30/19 at 2 am - Supine, 8 PM - Supine  7/31/19 at 12 am- Supine, 10 PM - Supine  8/1/19 at 2 am - Supine, 12 PM - Supine, 3:40 PM - Supine, 6 PM - Supine, 8 PM - Supine, 10 PM - Supine, 10 PM - Supine  8/2/19 from 4 am to 6 PM - No documented turning  8/7/19 at 6 PM - Supine  8/9/19 at 12 am - No documented turning  8/15/19 from 11 am to 3 PM - no documented turning  8/16/19 at 11 am - no documented turning, from 7	A 144		

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A 144	<p>Continued From page 123</p> <p>PM 6:30 am - no documented turning</p> <p>8/27/19 at 8:27 am - no documented turning, 12 PM - Supine, 8 PM - Supine</p> <p>8/28/19 at 12 am - Supine, 4 am - Supine</p> <p>8/31/19 at 2 PM - Supine</p> <p>9/3/19 at 3 PM - Supine, 7:15 PM - Supine</p> <p>9/5/19 from 9 PM to 1 am - no documented turning</p> <p>9/6/19 at 4 PM to 7:15 PM - no documented turning</p> <p>9/11/19 at 2 am - Supine</p> <p>9/12/19 at 1 am - Supine, 2 am - Supine, 4 am - Supine, 5 am - Supine, 6 am - Supine, 7 PM - Supine, 9 PM - Supine, 10 PM - Supine</p> <p>9/13/19 at 12 am - Supine</p> <p>During an interview on the morning of 9/20/19, Staff #S401 confirmed the findings and stated Patient #66 was noncompliant and would place himself in the supine position. Staff #401 was unable to provide documentation of Patient #66's noncompliance or the staffs re-educating the patient when Patient #66 was found in the Supine position.</p> <p>Review of Patient #66's treatment plan revealed the wound skin treatment plan was not added until 8/19/19 at 9:40 PM and was not updated to reflect Patient #66's continued non-compliance</p>	A 144			

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A 144	<p>Continued From page 124 with lying supine and interventions to assist with compliance such as re-education and the use of wedges for positioning.</p> <p>PATIENT #158</p> <p>Review of Patient #158's medical records revealed an elderly patient admitted on 6/13/19.</p> <p>On 6/17/19, the wound care nurse documented, Buttocks, scar tissue.</p> <p>On 6/24/19, the wound care nurse documented, right/left only, 5cm X 7cm with 34% external dermal.</p> <p>On 8/8/19, the wound care nurse documented, 9cm X 11.5cm with 90% and 10% pink base.</p> <p>On 7/20/19, the nurse's note reflected a small skin tear to sacrum. The wound was not measured.</p> <p>On 7/22/19, the nurse's note reflected (2) sacral wounds, the wounds were not measured.</p> <p>On 7/29/19, the wound care nurse documented - 8.5cm X 11.5cm with 100% adherent black neurotic tissue.</p> <p>Review of Patient #158's turning, and repositioning documentation revealed the following:</p> <p>6/24/19 at 7 PM - Supine, 11:00 PM- Supine</p> <p>6/26/19 at 1:00 am - Supine</p>	A 144			

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A 144	Continued From page 125  6/28/19 at 2:30 PM - Supine  6/29/19 at 11:00 PM - Supine  6/30/19 at 3:00 am - Supine  7/6/19 at 9:00 am - Semi fowlers (reclining on back side), 9:00 PM - Semi fowlers  7/20/19 at 3:00 PM - Supine  7/23/19 at 7:00 am - Semi fowlers  7/24/19 at 7:00 am - Semi fowlers  Review of the facility provided policy #431 PRESSURE INJURY PREVENTION AND TREATMENT (dated 09/2018) reflected, "Purpose: To outline a comprehensive regimen designed to prevent, identify, and manage pressure injury (ulcer); to provide the guidelines for identifying at-risk patient, and the specific factors placing them at risk for the development of pressure injury (ulcer).  Policy Statement: All inpatient of Harris Health System shall be assessed for pressure injury (ulcer) and the risk of its development. Appropriate standardized assessment tools shall be used to identify at-risk patients and specific modalities shall be utilized to prevent and treat pressure injury (ulcer).  F. PRESSURE INJURY: A localized injury to the skin and/or underlying tissue usually over a bony prominence; the result of pressure or pressure in combination with shear and/ or friction."	A 144			

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A 144	Continued From page 126  Review of the facility provided policy #4001 Wound Care (dated 03/03/2019) reflected, "Purpose: to establish patient care guidelines to be used when a wound care referral is received by Harris Health System Physical Therapy ... Procedure for Inpatient Referrals: 1. WOCNURSE will assess all consults regarding pressure ulcers, moisture management ..."  C.) Review of the facility provided (Undated) staff training, "HARRIS HEALTH SKIN CARE MODULES Module 2: Pressure Injury Staging ... WOUND MEASUREMENTS: Wounds are measured by Length X Width X Depth (LxWxD). This is the diameter from edge to edge of wound. Any tunneling/undermining must be measured and identified.  PATIENT #161  Review of Patient # 161's medical records reflected a 72-year-old-female admitted on 7/14/19 with a diagnosis of NSTMI (non-ST elevation myocardial incident)  On 7/16/19, the nurse documented a skin tear to buttock. The nursing documentation did not include measurements of the wounds.  On 7/17/19, the wound care nurse recorded the following:  Lower back: Suggest pressure injury DTI (deep tissue injury)	A 144			

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A 144	<p>Continued From page 127</p> <p>Measurements (LXWXD) (cm) 4x3.5x unable to determine</p> <p>Buttocks skin fold: Moisture related skin damage</p> <p>Measurements (LXWXD) (cm) 3x0.3x0.23.5x unable to determine</p> <p>On 7/17/19, a medial midline bruise. The nursing documentation did not include measurements of the wounds.</p> <p>On 7/10/19, an excoriation below breast. The nursing documentation did not include measurements of the wounds.</p> <p>On 7/22/19, fluid filled blister. The nursing documentation did not include measurements of the wounds.</p> <p>During an interview on the morning of 9/25/19, in the facility conference room, Staff #S546, confirmed the findings and stated, "The measurements are not there..."</p> <p>PATIENT #122</p> <p>Review of Patient #122's medical records revealed a 45-year-old-female with an open wound to RLE s/p debridement's for necrotizing fasciitis.</p> <p>The Physical Therapy Wound Care Evaluation dated 9/13/19 reflected the following:</p> <p>1. Dressing change by nursing: Frequency</p>	A 144			



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A 144	<p>Continued From page 128</p> <p>daily. Clean the wound with gauze moistened with dermal wound cleanser ... Wound Size (cm): L: 25.0cm W: 10.5cm D: 0.8cm</p> <p>Review of the nurses wound care and assessment notes dated 9/25/19, reflected the dressing was changed by the night shift; the nurse did not document the wounds size, width or depth.</p> <p>Patient#162</p> <p>Review of Patient #162's medical records revealed a 50-year-old-male admitted on 8/12/19 with Sezary Syndrome, a skin condition that places the skin at risk of developing rashes. Patient #162 developed 3 wounds to the scalp, due to the EEG monitor lead placements.</p> <p>On 8/22/19, Patient #162 developed a wound to the left ear. The scalp wounds and the ear wound were not clearly described or measured.</p> <p>PATIENT #159</p> <p>Review of Patient #159's medical records reflected a 61-year-old-female admitted on 8/14/19 with a sacral decubitus ulcer and left foot gangrene.</p> <p>On 8/16/19, the nurse documented a Stage 4 pressure wound; the nurse did not document the measurements or a description of the wound.</p> <p>On 8/16/19, the wound care nurse documented the wound at 6.5cmX5cmX4cm.</p>	A 144			

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A 144	<p>Continued From page 129</p> <p>PATIENT#160</p> <p>Review of Patient #160's medical records reflected a 64-year-old-male admitted on 6/26/19 with End Stage Renal Disease.</p> <p>On 6/26/19, the nurse documented- Skin intact.</p> <p>On 7/8/19, the nurse documented- right elbow, red swollen.</p> <p>On 7/10/19, the nurse documented- Left foot injury.</p> <p>On 7/11/19, the nurse documented- Rectum Skin tear, moisture related.</p> <p>On 7/11/19, the wound care nurse document, denuded, excoriated rectum.</p> <p>During an interview on the morning of 9/20/19, when asked if the wounds should be measured, Staff #S150 stated, "Per policy, yes" and confirmed the findings.</p> <p>During an interview on the morning of 9/25/19, in the facility conference room, Staff #S399 stated, "Once the wound is discovered the nurses are to remeasure the wound every Wednesday, if it hasn't improved by 0.2cm they have to put in a wound care nurse consult ... All wounds should be measured on admission by the nurses.</p> <p>(F) Hospital 1</p> <p>Based on a review of i-STAT Handheld and Precision Xceed Pro manufacturer's instructions,</p>	A 144			

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A 144	<p>Continued From page 130</p> <p>observation and confirmed in staff interview, hospital 1 failed to monitor humidity and failed to ensure end users were notified if temperatures were outside of acceptable ranges for 6 of 6 (station 15 area, Core D area, A Side Holding area, B Side holding area, Pod 7 area and the CPU area) Emergency Department areas.</p> <p>1. A review of the i-STAT-1 System Manual, Art: 714336-000G, Rev. Date: 02-Sep-08, page 2-2 states under Specifications: "Operating Temperature 16-30 °C (61-86 °F), Relative Humidity 90% (maximum) non-condensing"</p> <p>2. A review of the Precision Xceed Pro, Blood Glucose Monitoring System operating manual, ART: 17026 Rev. B 03/09, page 12-1 states under Specifications: "Monitor Operating Temperature: 15-40 °C (59-104 °F), Humidity: From 10% to 90% noncondensing</p> <p>3. During tour of the Emergency Department 09/20/2019, from 1110 to 1200 hours, it was observed that laboratory testing using the i-STAT Handheld and Precision Xceed Pro instruments was being performed in station 15 area, Core D area, A Side Holding area, B Side holding area, Pod 7 area and the CPU area.</p> <p>4. During the tour of the Emergency Department areas, it was observed that there was no chart for recording the room temperature or humidity of 6 of 6 areas (station 15 area, Core D area, A Side Holding area, B Side holding area, Pod 7 area, and the CPU area) available for review.</p> <p>5. A review of facilities management environmental monitoring records for the records</p>	A 144			

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A 144	<p>Continued From page 131</p> <p>for the Emergency Department area revealed no documentation of humidity, documentation of temperature but no documentation of an acceptable range.</p> <p>6. In an interview of staff S112 on 9/27/2019, at 0858 hours, in the computer room, he stated that facilities management monitors sensors on the wall. They take reading every 10 minutes and use the Texas Regulations (25 TAC 1330169(c) for acceptable temperature range of 70-75 degrees F. In addition he stated there is no notification to the Emergency Department if the readings are outside temperature ranges.</p> <p>7. In an interview of staff S112 on 9/27/2019 at 0903 hours in the computer room he stated that they did not monitor humidity.</p> <p>Key: i-STAT instrument - basic chemistry, blood gas and troponin testing Precision Xceed Pro - glucose testing</p> <p>(G) Laboratory Issues Hospital #2</p> <p>1. Quick Reference Guide for the i-STAT Handheld, Art: 720660-00K, Rev. Date: October 11, 2017, page 51 states under Specifications: "Operating Temperature 16-30 °C (61-86 °F), Relative Humidity 90% (maximum) non-condensing"</p> <p>2. Precision Xceed Pro, Blood Glucose Monitoring System operating manual, ART: 19306 Rev. A 12/09, page 12-1 states under Specifications: "Monitor Operating Temperature: 15-40 °C (59-104 °F), Humidity: From 10% to</p>	A 144		

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A 144	<p>Continued From page 132</p> <p>90% noncondensing</p> <p>3. During tour of the Emergency room on September 24, 2019, at 12:20 PM, it was observed that laboratory testing using the i-STAT Handheld and Precision Xceed Pro instruments was being performed on a counter near the "shock room" and in a small room marked "testing".</p> <p>4. The "testing" room was observed to have a room temperature chart posted but the testing area near the "shock room" did not. Neither area had any documentation of humidity level monitoring.</p> <p>5. Interview conducted in the laboratory on September 25, 2019, at 10:45 AM, S344, stated, "I don't think either instrument has any environmental specifications for humidity, so it has never been monitored".</p> <p>Key: i-STAT instrument - basic chemistry, blood gas and troponin testing Precision Xceed Pro - glucose testing</p> <p>1. Harris Health System Policy No: BBQ 5006.01/BBF 3015.03 titled Refrigerator, Freezer, and Platelet Quality Control states:</p> <p>IF THE ALARM SOUNDS " ...5. For failure of blood bank refrigerator:</p> <p>a. If the door is ajar, close it. Confirm proper temp.</p> <p>b. If door was closed, check the probe bottle on</p>	A 144		

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A 144	<p>Continued From page 133</p> <p>the top shelf to ensure that the probe is placed far enough into the liquid to measure the temperature properly. Check the level of liquid in the bottle; it should be near the top. Refill the bottle as necessary with anti-freeze solution.</p> <p>c. If there is a power failure and the alarm sounds, notify Engineering to restore the power.</p> <p>d. If the alarm remains on and the interior temperature is out-of-limits, removes the blood units to an acceptable refrigerator in the main laboratory ..."</p> <p>e. "Note: Never inactivate any alarm, even temporarily, without confirmation of the temperature of the equipment. Do not attempt to silence alarms through any other means except the temporary alarm silence switch."</p> <p>2. Observations on September 24, 2019, at 12:00 PM, in the Emergency Center, found that the emergency center staff failed to follow procedure when the alarm sounded on the Blood Bank Refrigerator where units of packed Red Blood Cells used for patient transfusions were stored.</p> <p>Alarm was manually activated by laboratory staff (S343, S344, S345, and S347) and surveyor. The following response to alarm was observed:</p> <p>a. EC staff from nearby unit desk came to the area where the alarm was sounding; looked around the area, checked the blanket warmer door, unit beneath the blanket warmer and stated, "I don't have any idea where that alarm is coming from".</p>	A 144			

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A 144	Continued From page 134  b. After the alarm continued to sound for another minute, a different EC staff member came from a room adjacent to the Blood Bank Refrigerator and said, "The Lab people are standing here so it is probably the refrigerator. Here it is" and turned the alarm off above the Blood Bank refrigerator.  c. Neither staff member checked to be sure the door on the refrigerator was closed, verified the Blood Bank Refrigerator temperature was within range or notify the laboratory or Engineering department.	A 144			
A 145	PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT CFR(s): 482.13(c)(3)  The patient has the right to be free from all forms of abuse or harassment.  This STANDARD is not met as evidenced by: Based on review of documents and interview, the facility failed to ensure patient rights to be free from all forms of abuse and neglect by failing to:  A.) Take timely action to ensure patient care needs were not neglected (a form of abuse) at Hospital #2 after repeated reports of patients not receiving vital medications on time due to the Labor and Delivery Unit not having access to the required equipment for administration of	A 145			

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A 145	<p>Continued From page 135</p> <p>medication. The facility was aware that Intravenous (IV) infusion equipment was not readily available to staff and neglected to identify problems associated with the timely distribution of IV infusion equipment. The facility neglected to take immediate actions to ensure vital IV infusion equipment was available for patient care. This neglect to take action repeatedly left patients with delays in receiving vital medication administration.</p> <p>B.) Thoroughly investigate and/or respond to an allegation of neglect in accordance with their policies and procedures for 1 of 1 patients reviewed (Patient #383) with an allegation of neglect reported on his behalf at facility #2. On 8/9/19, it was alleged Patient #383 was neglected when staff failed to ensure one to one supervision for patient safety of suicidal ideation and in accordance with his physician orders. The facility did not have evidence this allegation of neglect was thoroughly investigated and/or reported to the Texas Department of State Health Services (DSHS) in accordance with their policy and procedures and State Law.</p> <p>This deficient practice could compromise patient safety by failing to implement protections.</p> <p>Findings:</p> <p>A.) Review of incident reports for Labor and Delivery submitted in August 2019 was made. During the review, it was noted that on 8-13-2019, 8-17-2019, 8-23-2019, 8-28-2019, and 8-30-2019, patient care was delayed because</p>	A 145			



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A 145	<p>Continued From page 136</p> <p>staff could not get the necessary infusion pump to administer intravenous medications. Medications delayed included "time-critical antibiotic," Pitocin (medication necessary to augment labor), and IV fluids.</p> <p>Interview was conducted with Hospital #2 CNO on the afternoon of 9-25-2019 regarding actions taken because of non-availability of pumps. The CNO was asked if the problem with patient care being delayed due to infusion pumps not available had been submitted to the Quality Department for evaluation of the problem and identification of the possible solutions since this was a quality of care issue. The CNO confirmed that it had not been reviewed by the Quality Department.</p> <p>The CNO stated the hospital had enough IV pumps. He stated that he was aware that there was a delay in care as recent as the previous day on the Labor and Delivery unit due to no pump being available but insisted the problem wasn't with having enough pumps. The CNO explained that an inventory of pumps had been conducted and showed there were plenty of pumps available but there was shortage of IV poles that hold the pumps. The CNO confirmed that the plan to correct the problem was that IV poles had been placed on order. The CNO did not know how many poles had been ordered or when they would be in service. An inventory of IV pumps was provided the next day to show that the hospital had 801 Alaris IV pumps assigned to inventory. No inventory of IV poles was provided. No purchase order for IV poles was provided.</p>	A 145			

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A 145	<p>Continued From page 137</p> <p>While the list provided showed that there was possibly an adequate number of pumps in the hospital's inventory, it did not indicate the availability of the pumps. The CNO confirmed that the problem had not been sent to Quality Assessment and Performance Improvement (QAPI), therefore, QAPI was not tracking the availability of those pumps, tracking delays in care, analyzing the process for distributing those pumps, or aggregating and analyzing data to ensure that the actual cause of delays in patient care had been identified. No evidence was provided that the facility had taken immediate action to put temporary processes in place to ensure that patient care was not neglected resulting in the likelihood for bad patient outcomes due to patients not receiving necessary IV medications in a timely manner.</p> <p>B.) Review of the facility's Policy and Regulation titled, Abuse, Neglect, and Exploitation of Patients occurring at the system facilities effective 4/2017 indicated the following in part: Post investigation-2. The Accreditation and Regulatory Affairs Department shall make necessary notifications to regulatory agencies as required. There was not a specific named agency or phone number indicated.</p> <p>The policy indicated the "types of abuse, neglect and exploitation requiring investigation" were on page 9 and 10 indicating physical abuse/assault, sexual assault, verbal or emotional abuse, exploitation, and sexual harassment. Neglect was not indicated as a type of abuse that needed an investigation. The policy did not define Neglect except for neglect of a Child and Elderly.</p>	A 145			

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A 145	Continued From page 138  Review of the facility's Policy and Regulation titled, Mandatory Reporting Requirements and Notification Commitment last revised 7/12/19 indicated the following in part: Appendix A- Mandatory reporting indicated on page 6 that Abuse, Neglect, Exploitation, and/or Unprofessional/Unethical Conduct would be reported to the Texas Department of State Health Services [DSHS] (no other specific details were indicated). When to Report indicated to see Attachment D for time frames to report.  Review of Attachment D for reports of abuse, neglect, exploitation, unprofessional, or unethical conduct indicated the following:  a. Abuse/Neglect:  i. What to Report: [Facility] must report when it believes or knows information that would reasonable cause a person to believe that the physical or mental health or welfare of a patient who is receiving chemical dependency, mental health, or rehabilitation services has been, is, or will be, adversely affected by Abuse or Neglect caused by any person.  ii. Whom to Report to: The Texas Department of State Health Services, Patient Quality Care Unit, and Division for Regulatory Services. There was no phone number provided.  iii. When to Report: [Facility] must report this information "as soon as possible."  The policy did not define Neglect; except for	A 145			

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A 145	<p>Continued From page 139</p> <p>neglect of a Child, Elderly, or a Person with a Disability.</p> <p>Review of facility's Electronic Internal Reporting System (EIRS) File ID #151913 revealed an allegation reported 8/9/19 on behalf of Patient #383 by a nurse manager that alleged Neglect, Severity Level 1 - Unsafe condition when patient came to day surgery from Interventional Radiology (IR) and had suicidal ideations (SI). No report was received that the patient was on suicidal precautions. Patient had a physician order for one to one continuous supervision dated 8/4/19. The EIRS findings revealed the chart was reviewed. "No response from departmental leadership to date. Error on part of facility. Error reached patient. Error cause no harm. Level:3." Resolution/Outcome - Patient Safety Event Type: "Not applicable." File was closed on 9/6/19.</p> <p>Further review of the EIRS internal reporting system revealed all allegations of abuse, neglect, and exploitation were coded as "assault." The system does not allow an option for Neglect. This specific EIRS File ID #151913 allegation of Neglect was coded as "diagnosis/treatment" in the reporting system.</p> <p>Interview with Staff #S531 on 9/18/19 at 2:30 PM, was asked about reporting abuse and neglect allegations to a regulatory agency. Staff #S531 indicated the facility followed CMS [Centers for Medicare and Medicaid Services] guidelines. Staff #S531 stated she would "call in allegations of abuse that were substantiated" to the specified local (Houston) Zone Manager for the Patient</p>	A 145			

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A 145	<p>Continued From page 140</p> <p>Health Care Quality Unit, and indicated the local Zone Manager's phone number.</p> <p>Further interview on 9/19/19 at 9:30 AM with the Staff #S531 indicated the last abuse neglect allegation reported to the DSHS was on 11/28/2015 for sexual assault that was substantiated. Staff #S531 stated when allegations are substantiated after investigation then they are reported to the state [DSHS]. Staff #S531 stated, if the allegations were inconclusive, they were referred to Patient Safety as a Grievance. Unsubstantiated allegations are not reported to the state.</p> <p>Staff #S531 was interviewed on 9/19/19 at 10:00 AM regarding the EIRS File #151913 for Patient #383 and she indicated a report was entered in to the facility's EIRS because when the patient went to the IR suite the staff did not let the nurse know that he had one to one supervision for SI. Staff #S531 stated, there was a 20-minute delay (breach) of one to one supervision on 8/9/19 from 13:30 to 13:50 when the patient was in transition from IR to the Post-Anesthesia Care Unit (PACU). Staff #S531 stated the assigned one to one staff was responsible to complete 15 minute documented checks on the patient interventions flowsheet. Staff #S531 stated, this allegation (EIRS #151913) had not been reported to the state/DSHS because there had not been any response from the Radiology Department's Leadership and further stated, the Radiology Manager has left the position since this allegation. Staff #S531 confirmed there were not any statements available for review because this incident report was sent to the Radiology</p>	A 145			

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A 145	<p>Continued From page 141</p> <p>Manager for follow up and investigation. This EIRS incident was sent on 8/14/19 with a deadline of 8/21/19 to follow up and respond. Staff #S531 confirmed as of 9/19/19 there had not been any follow up from the department for this specific allegation. Staff #S531 confirmed this neglect allegation for Patient #383 was closed without a thorough/complete investigation or a determination if the allegation had been substantiated.</p> <p>Review of Patient #383's medical record revealed the following: On 8/4/19 at 04:35 AM, the nursing flowsheet documented this Patient was suicidal with a plan to kill himself. Patient admitted to past suicidal attempts multiple times. Requested one to one sitter and Psychiatric consult, with suicide precautions.</p> <p>Physician Order on 8/4/19 at 04:58 for a Patient Safety Assistant (PSA) continuous one to one supervision.</p> <p>Review of Patient #383's Nursing flowsheets revealed breaches in documentation on 8/9/19 from 19:15 to 21:30 by the PSA for the one to one supervision. In addition, the Patient Flowsheet record allowed a blocked section for documentation of the one to one continuous observation; but this area was not used and does not have documentation for Patient #383.</p> <p>CMS Guidelines define Neglect: for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm,</p>	A 145			

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A 145	Continued From page 142 mental anguish, or mental illness.	A 145			
A 174	<p>CMS Guidelines also suggest the hospital ensures a timely and thorough investigation of all allegations of abuse, neglect or mistreatment.</p> <p><b>PATIENT RIGHTS: RESTRAINT OR SECLUSION</b> CFR(s): 482.13(e)(9)</p> <p>Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.</p> <p>This STANDARD is not met as evidenced by: Based on review of documentation and interview, the facility failed to ensure restraints were discontinued at the earliest possible time according to the physician orders and facility policy for 1 of 8 Patients (Patient #382) reviewed for restraints at facility #2.</p> <p>Specifically, Patient #382 remained in 4 point restraints while nursing documentation indicated he was resting and subdued during assessments on 6/7/19 at 00:15 until released from restraints at 08:06AM (over 8 hours).</p> <p>Findings:</p> <p>Review of the facility's Policy Titled Restraint and Seclusion, last reviewed 06/2019 indicated that restraint and seclusion episodes will always be discontinued as soon as possible for the safety and well-being of the patient, regardless of the scheduled expiration of the order.</p>	A 174			

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A 174	<p>Continued From page 143</p> <p>Review of Patient # 382's records revealed the following restraint orders while Patient was in 2B Med/Surg Unit of Hospital #2:</p> <p>Restraint order 6/6/19 at 07:27 PM: Continuous for 4 hours for 4 point soft (Right/Left (R/L) Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/6/19 at 07:38 PM for Continuous for 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/6/19 at 08:14 PM for Continuous for 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order renewal on 6/6/19 at 23:45 (11:45 PM) for Continuous for 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/7/19 at 00:32 AM for Continuous X 4 hours for 4 point soft (R/L Wrist</p>	A 174			



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A 174	<p>Continued From page 144 and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/7/19 at 04:15 AM for Continuous X 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/7/19 at 04:22 AM for Continuous X 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/7/19 at 08:06 AM for Continuous X 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Restraint order 6/7/19 at 08:16 AM for Continuous X 4 hours for 4 point soft (R/L Wrist and R/L Ankle). Justification: Imminent risk of harm to self, others, or both. Discontinuation Criteria: Absence of Behavior that Required Restraint.</p> <p>Review of the Nursing Flowsheet documentation</p>	A 174			

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A 174	<p>Continued From page 145</p> <p>for Patient # 382's restraints revealed the following documentation: 4-point Restraint implemented 6/6/19 at 7:27 PM and 4-point Restraint discontinued 6/7/19 at 08:06 AM</p> <p>Condition impacting the need for restraint till present:</p> <p>6/7/19 at 00:15 AM, Dr notified continue restraint 0-Other Patient resting; Subdued.</p> <p>6/7/19 at 00:45 AM, Patient "Subdued."</p> <p>6/7/19 at 01:00 AM, Patient resting; Subdued, restraint loosened.</p> <p>6/7/19 at 01:23 AM, (Other) Patient resting, restraint loosed. 4 point restraints continued.</p> <p>6/7/19 at 01:30 AM, Patient resting; Subdued, restraint loosened.</p> <p>6/7/19 at 01:45 AM, Patient resting; Subdued, restraint loosened.</p> <p>6/7/19 at 2:00 AM, Subdued. Restraint loosened. Position changed and range of motion.</p> <p>6/7/19 at 05:38 AM, (Other) Patient resting, restraint loosened. 4 point restraints continued.</p> <p>6/7/19 at 08:06 AM, Restraints Discontinued.</p> <p>Patient #382 remained in a 4-point restraint from 6/6/19 at 7:27 AM until discontinued on 6/7/19 at 08:06 AM (over 12 hours). Nursing documentation indicated he was resting and</p>	A 174		

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A 174	<p>Continued From page 146</p> <p>subdued during checks on 6/7/19 at 00:15 until released from restraints at 08:06AM (over 8 hours).</p> <p>The behavior requiring restraint was absent while Patient #383 was resting and subdued documented on 6/7/19 at 00:15, 00:45, 01:00, 01:23, 01:30, 01:45, 02:00, and 05:38.</p> <p>Review of Nursing Flowsheet notes revealed the following:</p> <p>6/7/19 at 4:00 AM, Patient is subdued but has periods of agitations and aggression, combative, fighting against restraints. Four point restraints on.</p> <p>6/7/19 at 7:17 AM, Upon arrival, Patient is in 4 point restraints. Patient keeps saying how he wants to leave and randomly laughing. Patient talking to himself and keeps asking staff to let him go.</p> <p>During an interview on 9/24/19 at 10:15 AM, Staff #S677 confirmed Patient # 382 should have been released from his 4 point restraints when it was documented that he had been resting and subdued since the behavior requiring restraint was absent and he met criteria for the release of the 4 point restraints; first documented on 6/7/19 at 00:15AM.</p> <p>During an interview on 9/23/19 at 10:15, Staff #S360 stated violent restraints were to be removed from the patient when they were no</p>	A 174			

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A 174	Continued From page 147 longer exhibiting the behaviors. Staff #S360 stated the nurse can discontinue the restraints, remove, and if the patient becomes violent again, the nurse can get another restraint order to re-implement the restraint.	A 174			
A 178	<b>PATIENT RIGHTS: RESTRAINT OR SECLUSION</b> CFR(s): 482.13(e)(12)  When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1-hour after the initiation of the intervention -- o By a-- - Physician or other licensed independent practitioner; or - Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.  This STANDARD is not met as evidenced by: Based on record review of facility documentation and staff interviews, the facility failed to have a physician or other licensed independent practitioner (LIP) assess the patient face-to-face within 1-hour after the initiation of a restraint used for the management of violent or self-destructive behaviors for 4 of 8 patients (Patient's #379, #391, #394, and #395) reviewed for restraints at facility #2.  1.) Patients were being administered psychotropic emergency medications (also known as Chemical Restraints) used to control violent	A 178			

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A 178	<p>Continued From page 148</p> <p>behaviors and was not assessed face-to-face within 1-hour after the initiation of the emergency medications to evaluate the intervention and,</p> <p>2.) Patients had 4-point physical restraints implemented to control violent behaviors and was not assessed face-to-face within 1-hour after the initiation of the 4-point restraints.</p> <p>Findings:</p> <p>Patient #394</p> <p>a.) Review of Patient #394's Physician Orders (PO) dated 9/3/19 at 23:57 revealed an order for violent restraint, 4 point due to imminent risk. Patient agitated, restless, verbally aggressive, and continues biting.</p> <p>Review of the nursing flowsheet revealed this restraint was implemented at 23:58 and discontinued at 00:30 (32 minutes later).</p> <p>Patient #394's record on 9/3/19 at 23:57 documented a face-to-face physician evaluation and a violent restraint provider note at the exact time of the PO. These physician assessments were documented before the implementation of Patient #394's 4-point restraint at 23:58 and not after the implementation to evaluate and assess the intervention.</p> <p>Further review of Patient #394's record revealed there was not a face-to-face evaluation conducted within 1 hour after the initiation of the 4-point intervention on 9/3/19 at 23:58.</p>	A 178			

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A 178	<p>Continued From page 149</p> <p>b.) Patient #394's record documented the following psychotropic medications administered due to a Psychiatric Emergency including violent behaviors.</p> <p>PO 9/4/19 at 03:01 for Haldol 5 milligrams (mg) intramuscular (IM) one time stat now. Psychiatric emergency - yes. For aggression. Medication Administration Record (MAR) - Administered 02:30 without a verbal order (prior to the order placed in the record). There was no face-to-face evaluation documented within 1 hour after the initiation of emergency medication used for violent behaviors on 9/4/19 at 2:30 AM.</p> <p>PO 9/4/19 at 09:19 Ativan 2mg Intravenous (IV) one-time push 1mg. Psychiatric Emergency - Yes. Emotional lability. Initiate this psychoactive medication for psychiatric stabilization, safety, and management of the patient's psychiatric crises. MAR- Administered at 09:25. There was not a face-to-face evaluation conducted within 1 hour after the initiation of the emergency medication used for violent behaviors on 9/4/19 at 09:25 AM.</p> <p>Patient #395</p> <p>a.) PO on 9/3/19 at 17:52 for a violent restraint 4 point, imminent risk. Modification to a 3-point restraint: do not restraint left leg due to ortho boot. Nursing Flowsheet documented the 3-point Restraint implemented 9/3/19 at 18:00 due to aggressive behaviors, continues verbal threats, and lunging.</p> <p>9/3/19 at 17:59 indicated a face to face physician evaluation for verbally threatening, observed</p>	A 178			

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A 178	<p>Continued From page 150</p> <p>patient, current order for restraints should be continued. Patient hitting, verbally threatening. This evaluation was completed just before the implementation of the 3-point restraint at 18:00.</p> <p>b.) Emergency Medications administered:</p> <p>PO 9/3/19 at 18:29, Benadryl 50mg/ml injection, 50 mg IM for aggression one time use only for psychiatric emergency. MAR - Administered at 18:08</p> <p>PO 9/3/19 at 18:29 Versed (midazolam) one-time dose 5mg IM. MAR- Administered at 18:08</p> <p>Patient #395's record there was not a documented face to face Physician evaluation conducted within 1 hour after the initiation of the emergency medications used for violent behaviors; Versed and Benadryl on 9/3/19 at 18:29.</p> <p>Patient #379</p> <p>a.) PO 7/6/19 at 17:21- Violent Restraint order 4-point Imminent risk. Release when absence of behavior. Nursing Flowsheet documented restraint implemented 17:15- Patient #379 was placed into a 4 point (2 right/left wrist, and 2 right/left ankle) physical restraint.</p> <p>17:15- the Resident Medical Doctor (MD) documented a "Violent Restraints Provider Note" indicating the patient was violent and aggressive and required restraints in order to keep him and others safe. This note was as the exact time of</p>	A 178			

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A 178	<p>Continued From page 151</p> <p>the implementation of the 4-point restraint (17:15), and not after the implementation to evaluate the intervention. There was no face-to-face evaluation conducted within 1 hour after the initiation of this 4-point restraint used for violent behaviors on 7/6/19 at 17:15.</p> <p>b.) PO 7/6/19 at 17:13 - Lorazepam 2mg IV stat once- Psychiatric Emergency- Yes. Justification for use: one time use only for psychiatric emergency. Initiate this psychoactive medication for psychiatric stabilization, safety, and management of patient's psychiatric crisis - Answer, aggression. The MAR indicated this medication Administered at 17:30. There was not a face-to-face evaluation conducted within 1 hour after the initiation of the emergency medication used for violent behaviors on 7/6/19 at 17:30.</p> <p>Interview with the Quality Coordinator Staff #S677 on 9/24/19 at 10:00 AM, during the review of Patient #379's records stated the facility does not use Chemical Restraints. Staff #S677 stated the facility did not interpret the use of Emergency Medications administered in a Psychiatric Emergency as a Restraint, stating, it was a "gap in our quality." Staff #677 confirmed there was no physician or LIP one-hour face-to-face evaluation completed within one hour after the implementation of 4-point restraint and emergency medication on 7/6/19 for Patient #379.</p> <p>Patient #391</p> <p>Review of Patient #391's PO dated 8/28/19 at 04:26, revealed an order for a 4-point soft R/L</p>	A 178			



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A 178	<p>Continued From page 152</p> <p>wrist and r/l ankle imminent risk of harm to self, others, or both. The nursing flowsheet indicated restraint implemented at 04:26.</p> <p>Review of the Physician's One-hour face-to-face evaluation on 8/28/19 at 04:26AM, was documented at the exact time of the implementation of the 4-point restraint and not after the implementation to evaluate the intervention.</p> <p>Interview with the Quality Coordinator Staff #S677 on 9/24/19 at 11:30 AM, during the review of Patient #391's records indicated the physician is usually at the patient's bedside during the implementation of restraints and is putting in the orders into the patient's electronic medical record during the time of implementation. Staff #S677 confirmed there was no additional face-to-face evaluation completed in Patient #391's records after the implementation of the 4-point restraint at 4:26.</p> <p>Interview with Staff #S671 on 9/26/19 at 09:50 AM, confirmed the facility had not identify the use of emergency psychotropic medications as a restraint and further stated, the Physicians were indicating the facility did not use "Chemical Restraints." Staff #S671 confirmed the facility had not ensured Patients that were being administered psychotropic emergency medications used to control violent behaviors (also known as Chemical Restraints) were assessed face-to-face within 1-hour after the initiation of the emergency medications because it had not been built into the electronic record platform to populate the face to face physician evaluation.</p>	A 178			

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A 178	<p>Continued From page 153</p> <p>Facility Policies Reviewed:</p> <p>Restraint and Seclusion last reviewed 06/2019, indicated the following in part,</p> <p>A.) The policy defined Restraint to include "A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition."</p> <p>The policy defined Chemical Restraint as a medication used to restrict a patient's freedom of movement or manage a patient's behavior and is not a standard treatment or dosage for the patient's condition.</p> <p>Types of Restraints included: c. Chemical Restraint: The use of a drug as a restraint requires two (2) fundamental criteria:</p> <p>i. It is used to restrict the patient's behavior and freedom of movement; and</p> <p>ii. It is not a standard treatment of dosage for the patient's condition.</p> <p>iii. No patient shall be treated with a chemical restraint.</p> <p>B.) In the area of Patient Monitoring and Documentation for Violent or Self-Destructive behavior revealed, the policy did not specify the requirement for a physician or LIP face-to-face evaluation requirement within 1 hour after the</p>	A 178		

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A 178	<p>Continued From page 154 initiation of a restraint.</p> <p>C.) In the area of patient Re-evaluation indicated, "Following the initial application of restraint/seclusion, the MD [Medical Doctor] conducts and in-person assessment at least every 4 hours." There was no indication of the one-hour face-to-face requirement after initiation of restraints.</p> <p>D.) The policy indicated on page 12, Administering Emergency Medication:</p> <ol style="list-style-type: none"> <li>1. Staff is to use the least restrictive method of administering the medication to avoid or reduce the use of force.</li> <li>2. Physician orders for physically holding a patient to administer emergency medication is required prior to the application of the restraint (use of force).</li> <li>3. A physical hold is terminated as soon as the medication is administered.</li> <li>4. If physical holding for forced medication is necessary with a violent patient, the one (1) hour face-to-face evaluation requirement would also apply.</li> </ol> <p>Further review of the entire policy revealed, there was no direction regarding the 1-hour face-to-face evaluation requirement by a physician or LIP except for the use of Administering Emergency Medication as specified above indicating, "If physical holding for</p>	A 178		

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A 178	<p>Continued From page 155</p> <p>forced medication is necessary with a violent patient, the one (1)-hour face-to-face evaluation requirement would also apply." There were no other procedures regarding the one-hour face-to-face.</p> <p>In the area of Quality Monitoring for Restraints in the policy revealed restraints would be monitored and evaluated on a continual basis as part of the facility's Quality Management System which included "Evidence of face-to-face assessment by MD within one hour of restraint/seclusion application."</p> <p>Review of the facility's policy titled, "Consent to Treatment with Psychoactive Medication" effective 03/11, indicated the following, in part:</p> <p>F. Administration of psychoactive medication in emergency situations:</p> <p>1. The physician shall issue and order to administer psychoactive medication to a patient without the patient's consent. The physician will document in the clinical record:</p> <p>a. The necessity of the order in specific medical and behavioral terms;</p> <p>b. Other generally accepted less accepted less intrusive forms of treatment which the physician has evaluated, but rejected; and</p> <p>c. The reasons those treatments were rejected.</p> <p>Further review of the entire policy revealed there</p>	A 178		

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A 178	Continued From page 156 was no direction regarding the 1-hour face-to-face evaluation requirement by a physician or LIP after the initiation of psychoactive emergency medication without the patient's consent.	A 178			
A 263	Interview with Staff #S671 on 9/23/19 at 11:00 AM, confirmed the facility did not have any additional policies regarding the use of Emergency Psychotropic medications administered to patients to control violent behaviors except for the guidelines for administering psychoactive medication in emergency situations in the policy titled Consent to Treatment with Psychoactive Medication, effective 3/11. QAPI CFR(s): 482.21  The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.  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); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.  The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	A 263			

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A 263	<p>Continued From page 157</p> <p>This CONDITION is not met as evidenced by: Based on review and interview, the hospital system failed to:</p> <p>A. follow their own Quality Manual 2019 to assist the System Pavilions with oversight, support, or continual improvement of quality patient care, to ensure safe and efficient treatment in Hospital #1 and #2, and Outpatient Services (ACS) of 3 Pavilions.</p> <p>B. the Facility's Quality Assessment Performance Improvement Committee failed to develop and implement a robust system which addressed all aspect of dialysis care and services in the facility (Hospital #1). Failed to ensure staff providing care and services to patients receiving hemodialysis treatment were assessed for competency.</p> <p>C. take timely action to ensure patient care needs were not neglected (a form of abuse) at Hospital #2 after repeated reports of patients not receiving vital medications on time due to the Labor and Delivery Unit not having access to the required equipment for administration of medication. The facility was aware that Intravenous (IV) infusion equipment was not readily available to staff and neglected to investigate and identify problems associated with the timely distribution of IV infusion equipment. The facility neglected to take immediate actions to ensure vital IV infusion equipment was available for patient care. The failure to take action repeatedly left patients with delays in receiving vital medication administration.</p>	A 263			

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A 263	Continued From page 158  D. ensure the laboratory services were integrated into the hospital-wide QAPI program and failed to implement strategies and monitor the effectiveness of corrective actions the laboratory implemented.  Refer to Tag A0283  E. to include contracted services in the Quality Assurance Performance Improvement (QAPI) process to ensure patient safety.  Refer to Tag A0308	A 263			
A 283	QUALITY IMPROVEMENT ACTIVITIES CFR(s): 482.21(b)(2)(ii), (c)(1), (c)(3)  (b) Program Data (2) [The hospital must use the data collected to - .....] (ii) Identify opportunities for improvement and changes that will lead to improvement.  (c) Program Activities (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care.  (3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to	A 283			

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A 283	<p>Continued From page 159 ensure that improvements are sustained.</p> <p>This STANDARD is not met as evidenced by: Based on review of documents and interview, the facility failed to:</p> <p>A. follow their own Quality Manual 2019 to assist the system Pavilions with oversight, support, or continual improvement of quality patient care to ensure safe and efficient treatment.</p> <p>B. the Facility's Quality Assessment Performance Improvement committee failed to develop and implement a robust system which addressed all aspect of dialysis care and services in the facility (Hospital #1). Failed to ensure staff providing care and services to patients receiving hemodialysis treatment were assessed for competency.</p> <p>C. Take timely action to ensure patient care needs were not neglected (a form of abuse) at Hospital #2 after repeated reports of patients not receiving vital medications on time due to the Labor and Delivery Unit not having access to the required equipment for administration of medication. The facility was aware that Intravenous (IV) infusion equipment was not readily available to staff and neglected to investigate to identify problems associated with the timely distribution of IV infusion equipment. The facility neglected to take immediate actions to ensure vital IV infusion equipment was available for patient care. The failure to take action repeatedly left patients with delays in</p>	A 283			



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A 283	Continued From page 160 receiving vital medication administration.  D. ensure the laboratory services were integrated into the hospital-wide QAPI program and failed to implement strategies and monitor the effectiveness of corrective actions the laboratory implemented.  Review of the facility Quality Manual 2019 revealed, the facility has a guide for the "Governance, Structure, and Leadership Responsibilities". The Manual revealed a community owned integrated system for the following Pavilions:  "1. Two (2) acute care hospitals 2. Sixteen (16) Community Health Centers, 3. Three (3) Pediatric and Adolescent Health Centers, 4. Nine (9) Homeless Shelter Sites, 5. Five (5) School Based Clinics, 6. Six (6) Mobile Health Clinics, 7. Two (2) Specialty Clinic Sites, 8. Five (5) Same-Day Clinics, 9. Dental Center, 10. Dialysis Center, 11. Contracted Outside Medical Services,	A 283			

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A 283	<p>Continued From page 161</p> <p>12. "Ask My Nurse" 24/7 Telephone Nurse Triage line,</p> <p>13. Emergency Medical Services Fleet,</p> <p>14. Ambulatory Surgery Center.</p> <p>B. Process Interaction: The processes within _____ Health System Quality Management System are interrelated."</p> <p>The listed Pavilions have been placed in three categories for quality reporting. Hospital #1, Hospital #2, and Out Patient Services (ACS). The Quality Manual 2019 instructed the reader on a hierarchy of reporting which started with the following,</p> <p>Medical Staff Committees Department/Service Committees/Councils Physical Environment System Level Committees Medical Executive Board and pavilion Medical Executive Committee.</p> <p>An interview was conducted with Staff #S738 on the morning of 9/24/19. Staff #S738 reported that if the individual departments had recognized a problem that could not be addressed and corrected in a timely manner then it should be brought to the director of the unit. Other options were to use the committees at the department level but was not necessary. The issues could be brought to the Pavilion Quality Review Council (QRC) that meets on a monthly basis.</p>	A 283			

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A 283	<p>Continued From page 162</p> <p>Quality Review Council (QRC)</p> <p>"The QRC provides oversight for the Quality Management System at the Pavilion level. Each Pavilion has its own QRC. The QRC has the responsibility and authority to determine the Quality Management System has been effectively implemented and maintained at the Pavilion. The QRC is responsible for measurement, monitoring and analysis of the National Integrated Accreditation for Healthcare Organizations (NIAHO) QM.7 Standard Requirements (SR).1-SR.18 quality of care metrics and other regulatory survey findings. The QRCs develop performance goals that are in alignment with the _____ Health System strategic objectives. In addition, all accredited/certified programs are required to routinely report (minimum of once year) outcomes and performance metrics, to QRC. The QRCs may also initiate performance improvement teams for issues that are unique to the departments within the pavilion."</p> <p>Once the information has been addressed in the QRC at the Pavilion level, that information and data would be reported to the Quality Governance Council (QGC).</p> <p>Quality Governance Council (QGC)</p> <p>"3. Quality Governance Council (QGC) The QGC provides executive oversight for _____ Health Quality Management System to support and facilitate the continual improvement of quality health care. The QGC has the responsibility and authority to determine if the Quality Management</p>	A 283			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>450289</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>09/27/2019</b>
NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 283	<p>Continued From page 163</p> <p>System (QMS) has been effectively implemented and maintained. The QGC ensures conformance to the National Integrated Accreditation for Healthcare Organizations (NIAHO) standards and other statutory requirement as stipulated by State and Federal agencies ...."</p> <p>"top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. This review shall include assessing for risks, opportunities, and the need for changes to the quality management system, including the quality policy and quality objectives.</p> <p>The review includes information on: a) The status of actions taken from previous management reviews, b) Changes in external and internal issues that are relevant to the quality management system, c) Information on the performance and effectiveness of the quality management system, including trends in: Customer satisfaction and feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and conformity of products and services, nonconformities and corrective actions, monitoring and measurement results, audit results, the performance of external providers, d) The adequacy of resources, e) The effectiveness of action taken to address risks and opportunities, f) Opportunities for improvement.</p> <p>The review also includes the decisions and actions related to: a) Opportunities for improvement, b) Any need for changes to the quality management system, c) Resource needs."</p>	A 283			

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A 283	Continued From page 164  BOT Quality Committee  "This is a committee of the Board of Trustees that oversees the Quality Safety and Performance Improvement (PI) Programs of ____ Health System in order to maintain high quality service, patient and staff safety, and overall satisfaction within ____ Health System."  Governance Board of Trustees  "Governance: Board of Trustees the ____ Health System Board of Trustees (BOT) is the governing body of ____ Health System. It has the ultimate authority and responsibility for the review, approval, and monitoring of ____ Health System's Quality Management System. The BOT ensures that an integrated plan is implemented throughout ____ Health System. The BOT designates the President/Chief Executive Officer as the executive agent who oversees the operation of the organization's Quality Management System. Refer to the Harris County Hospital District Board of Trustees Bylaws."  Rehabilitation Department Hospital #2  A tour was conducted in Hospital #2's inpatient Rehabilitation Department on 9/17/19. During a visit with the Physical therapy department staff, a daily patient census board for 9/17/19 revealed 96 patients would need a visit from the PT/OT department. Staff #733 confirmed, he did not have enough staff currently to cover that number	A 283			

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A 283	Continued From page 165 of patients. Staff #733 stated, he had only 5 PT's.  An interview with Staff #S733 was conducted on 9/17/19 concerning the staffing issues in the therapy department of Hospital #2 and if the issues were being addressed through the Quality Assessment Performance Improvement (QAPI) process. Staff #733 reported that they have had two issues, inappropriate PT evaluations and staff shortage. Staff #733 stated that he had hired a PT this week, but she was in orientation. Staff #S733 reported that he has openings he was trying to fill. Staff #733 stated that he had recently gone to the UR committee meeting to meet with physicians concerning the inappropriate evaluation orders. Staff #733 provided the surveyor with a handout that he had discussed with the physicians in the Utilization Meeting for appropriate referrals. Staff #733 stated, he had not taken the issues to Quality Assessment Performance Improvement (QAPI) yet because they were working on the problem on the departmental level. Staff #733 confirmed that they had been working on the problems for two years. Staff #733 stated that he reported data to QAPI but did not have an active Performance Improvement (PI) process. Staff #733 stated that they would work out all the problems, implement the changes and then take it to QAPI. There was no discussion found in the meeting minutes for QAPI or the BOT to ensure the department had funding and support to hire additional staff to prevent missed visits. Review of the QRC calendar for reporting revealed the Rehabilitation Services were to report quarterly to QAPI. The department reported the 1st quarter but did not report in May 2019. Staff #116 confirmed on 9/18/19 that Rehabilitation Services missed	A 283			

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A 283	<p>Continued From page 166 reporting in May of 2019. There was no documentation found that QAPI was assisting the Rehabilitation Department of Hospital #2 with oversight, support, or continual improvement of quality patient care concerning the high volume of missed visits.</p> <p>Patient charts reviewed on 9/18/19 revealed Hospital #2 failed to ensure adequate numbers of physical therapy (PT) staff were available to ensure timely evaluations, safe and efficient treatment, in 3 of 3 (432, 433, and 435) of 4 (432-435) patients.</p> <p><b>Contracted Services</b></p> <p>Review of the contracted services revealed, no contracted services were monitored through the QAPI process for any of the pavilions (Hospital #1, #2, or the ACS). Review of the Board of Trustee Minute Meetings from 9/18 -8/19 revealed, the contracted service contracts were approved during the meetings but there was no data that QAPI had assessed the services provided. There was no documented evidence provided that contracted services had reported to QAPI to ensure patient safety, improved quality of care, or improvement actions.</p> <p>An interview was conducted with Staff #742 on 9/25/19 at 1:30 PM. Staff #743 confirmed that the contracted services are approved at the BOT level and are not going through the QAPI process.</p> <p>Review on 09/24/2019 of a sample of hemodialysis staffs' personnel and training</p>	A 283			

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A 283	<p>Continued From page 167</p> <p>records revealed no evidence that the Facility's Quality Assessment Performance Improvement Committee ensured staff providing care and services to patients receiving hemodialysis treatment were assessed for competency:</p> <p>Patient Care Technician #S42 Review on 09/20/2019 of Patient Care Technician's #S42's Learning and Resource Center Education History Report, dated March 22, 2018, January 12th 2019 revealed he was hired to the facility on November 26, 2003. Review of the record revealed no evidence of current skills assessment completed on the Patient Care Technician for hemodialysis.</p> <p>Registered Nurse #S41 Review on 09/20/2019 of Registered Nurse (S41's) Orientation Skills Assessment Checklist revealed documentation which indicated the most current hemodialysis skills check list was dated 08/27/08. Review of the record revealed no evidence of current skills assessment completed on the Registered Nurse for hemodialysis.</p> <p>Patient Care Technician #S47 Review on 09/20/2019 of Patient Care Assistant #S47's Competency Based Clinical Orientation Tool dated 08/26/2019 revealed she was hired to the facility on 08/18/2012. Review of the record revealed the skills assessment was completed by the staff verbalizing the task. There was no demonstration of the tasks documented. Review of the record revealed no evidence of current skills assessment completed on the Patient Care Technician for hemodialysis.</p>	A 283			



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A 283	Continued From page 168  Registered Nurse #S43 Review on 09/21/2019 of Registered Nurse #S43's Orientation Skills Assessment Checklist revealed documentation which indicated the most current hemodialysis skills checklist on file was dated 01/04/13 - 2/9/13. There was no current skills assessment competency for hemodialysis/testing for total chlorine in water used for hemodialysis of patients.  Review of a Learning and Resource Center Education History Report for Registered Nurse #S43, dated March 2018 - September 2019 revealed no evidence of skills assessment completed on the Registered Nurse.  During a review of the personnel records with facility's staff #S308, on 09/20/2019 at 9:00 a.m., who had provided the personnel record to the Surveyor, she stated the unit had no documentation that staff in the hemodialysis unit had conducted skills assessment for the hemodialysis direct care staff.  During an interview on 09/20/2019 at 2:00 p.m. with the Vice President of Nursing for the hospital system, she said the facility did not have or implemented a skills assessment for hemodialysis.  Hospital 2  Review of incident reports for Labor and Delivery submitted in August 2019. During the review, it was noted that on 8-13-2019, 8-17-2019,	A 283			

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A 283	<p>Continued From page 169</p> <p>8-23-2019, 8-28-2019, and 8-30-2019 patient care was delayed because staff could not get the necessary infusion pump to administer intravenous medications. Medications delayed included, "time-critical antibiotic," Pitocin (medication necessary to augment labor), and IV fluids.</p> <p>Interview was conducted with Hospital #2 CNO on the afternoon of 9-25-2019 regarding actions taken because of non-availability of pumps. The CNO was asked if the problem with patient care being delayed due to pumps not available had been submitted to the Quality Department for evaluation of the problem and identification of the possible solutions since this was a quality of care issue. The CNO confirmed that it had not been reviewed by the Quality Department.</p> <p>The CNO stated the hospital had enough IV pumps. He stated that he was aware that there was a delay in care as recent as the previous day on the Labor and Delivery unit due to no pump being available but insisted that the problem wasn't with having enough pumps. The CNO explained that an inventory of pumps had been conducted and showed there were plenty of pumps available but there was shortage of IV poles that hold the pumps. The CNO confirmed that the plan to correct the problem was that IV poles had been placed on order. The CNO did not know how many poles had been ordered or when they would be in service. An inventory of IV pumps was provided the next day to show that the hospital had 801 Alaris IV pumps assigned to inventory. No inventory of IV poles was provided. No purchase order for IV poles was provided.</p>	A 283			

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A 283	Continued From page 170  While the list provided showed that there may be an adequate number of pumps in the hospital's inventory, it did not indicate the availability of those pumps for patient use. The CNO confirmed that the problem had not been sent to Quality Assessment and Performance Improvement (QAPI), therefore, QAPI was not tracking the availability of those pumps, tracking delays in care, analyzing the process for distributing those pumps, or aggregating and analyzing data to ensure that the actual cause of delays in patient care had been identified. No evidence was provided that the facility had taken immediate action to put temporary processes in place to ensure that patient care was not neglected resulting in the likelihood for bad patient outcomes due to patients not receiving necessary IV medications in a timely manner.  1. A review of the Laboratory 2019 Performance Improvement Departmental Semi-Annual Evaluation Executive Summary for Hospital 1 revealed for Microbiology a goal of 100% optimal fill volume of 8-10 ml for BD Bactec Plus Aerobic/F Culture Vials . The laboratory monitors fill volume for adult critical care and EC (Emergency Center).  2. Review of the Hospital #1 Microbiology Lab 2019 PI Summary Report Blood culture volume for Q1 2019 revealed that 68.1% (2421 of 3552 blood culture bottles that were monitored for correct fill volume) failed to meet the requirements for fill volume. Review of Q2 2019 blood culture fill volume revealed 68% (1657 of 2437 blood culture bottles) failed to meet the	A 283			

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A 283	<p>Continued From page 171</p> <p>requirements for fill volume. For Q2 2019 June data was not included due to issues with Epic Beaker Reports.</p> <p>a. Q1/2 2019 dropped to 31.91% of collected culture bottles containing the optimal volumes required by the manufacturer. This was a decrease of 16.39% from 2018.</p> <p>b. A review of laboratory quality assurance records revealed they had been working on the problem of blood culture fill volumes since at least August of 2018.</p> <p>c. A review of laboratory quality assurance records revealed the laboratory, at the department level, initiated a corrective action plan that involved communication with departments about optimal volume requirements, quick reference guides and manufacturer collection training materials to nurse leadership.</p> <p>d. The August 2019 Corrective Action Plan root causes identified by the laboratory were:</p> <p>(1) Microbiology Laboratory provided unit based summaries, Quick reference Guides and Manufacturer Training Guides to Nursing Leadership without receiving leadership's feedback.</p> <p>(2) Lack of continuing education and competency assessments within the individual blood culture collection departments.</p> <p>(3) Lack of Microbiology ability to provide detailed summaries to include collector's identity for the outliers in order for Nursing Leadership to follow up on... due to issues with EPIC Beaker</p>	A 283		

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A 283	<p>Continued From page 172 reports</p> <p>e. In August 2019 the Department of Pathology 2019 Q1/Q Performance Improvement Report Improvement Plan for fill volumes revealed the laboratory sent another request for a meeting with Quality Management and Patient Safety Department.</p> <p>3. In an interview of the staff S751 on 09/26/2109, in the Galveston conference room, he confirmed the issue of blood culture fill volumes identified in 2018 was not brought to ERC until July 2019.</p> <p>4. In an interview with staff S737 on 09/25/2019, in the Dallas conference room, she stated that Laboratory meet with quality twice a year in May and November.</p> <p>B. The hospital failed to ensure the Hospital #1 transfusion of blood/blood components procedure included objectively defined transfusion reaction signs and symptoms to ensure transfusion reactions were promptly investigated.</p> <p>Findings:</p> <p>1. Review of the Facility policy, "Administration of Blood and Blood Components and Blood Derivatives" and "Appendix A Administration of Blood and Blood Components and Blood Derivatives" revealed, the policy failed to include objectively defined transfusion reaction symptoms to ensure transfusion reactions were promptly investigated.</p>	A 283			

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A 283	<p>Continued From page 173</p> <p>II. Administration of Blood/Blood Components: ...</p> <p>If signs/symptoms of transfusion reaction are noted at any time during the transfusion, immediately stop the transfusion and follow the Transfusion reaction protocol.</p> <p>2. In an interview in Hospital (1) conference room at 1320 hours on 9/23/19, with Staff #S311 and after her review of the above policy, she confirmed that the "Administration of Blood and Blood Components and Blood Derivatives" policy did not define signs and symptoms of a transfusion reaction, such as back pain, chills, flushing, shortness of breath, itching, changes in temperature, blood pressure, pulse, or oxygen saturation, anaphylaxis, or cardiac arrest.</p> <p>Code of Federal Regulations Part 493, 493.1271(e); Standard: Investigation of transfusion reactions</p> <p>(e) Investigation of transfusion reactions.</p> <p>(e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.</p> <p>(e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are</p>	A 283			

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A 283	<p>Continued From page 174</p> <p>reviewed to assure they are adequate to ensure the safety of individuals being transfused.</p> <p>C. The hospital failed to ensure the Hospital #1 Point of Care Testing policy and procedures (policy 4398) were approved by the laboratory director.</p> <p>Findings:</p> <p>1. Review the Hospital #1 nursing "Point of Care Testing" policy and procedures # 4398 revealed, the procedure was not reviewed and approved by the laboratory director of Point of Care.</p> <p>    a. A review of the Hospital #1 nursing "Point of Care Testing" policy 4398 revealed, it was approved by the administrative director of Pathology, not the laboratory director.</p> <p>    b. A review of laboratory Point of Care procedures on 09/27/2019 at 0912 hours revealed, the laboratory developed policies and procedures "i-STAT Procedure" #POC.PC.2.570.2.08.02 and "Precision XceedPro Glucometer" procedure #POC.PC.2.500.11.10.03 were approved by the laboratory director of Point of Care.</p> <p>2. In an interview with staff #S311 at 0900 hours on 9/27/2019, she confirmed the administrative director was #S751, not the laboratory director of Point of Care.</p> <p>3. In an interview of staff #S751 at 0915 hours on 9/27/2019, he confirmed the laboratory developed</p>	A 283			

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A 283	Continued From page 175 procedures for point of care testing approved by the laboratory director were located in Media Lab.	A 283			
A 308	Code of Federal Regulations Part 493, 493.1251; Standard: Procedure Manual:"(d) Procedures and changes in procures must be approved, signed and dated by the current director before use." 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: Review of the contracted services revealed, no contracted services were monitored through the QAPI process for any of the pavilions (Hospital #1, #2, or the ACS). Review of the Board of Trustee Minute Meetings from 9/18 -8/19 revealed, the contracted service contracts were approved during the meetings but there was no data that QAPI had assessed the services provided. There was no documented evidence provided that contracted services had reported to QAPI to ensure patient safety, improved quality of care, or improvement actions.  An interview was conducted with Staff #S742 on 9/25/19 at 1:30 PM. Staff #743 confirmed that the contracted services are approved at the BOT	A 308			



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NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 308	Continued From page 176 level and are not going through the QAPI process.	A 308			
A 385	<b>NURSING SERVICES</b> 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 <b>CONDITION</b> is not met as evidenced by: Based on observation, interview, and record review, the facility failed to provide an organized nursing service:  A. The hospital failed to ensure that clear lines of authority had been established to show there was only one hospital-wide, unified nursing service. The organizational chart and job description for the Chief Nursing Officer (CNO) position showed that each campus location (Hospital 1 & 2) had a different CNO with lines of authority and designated responsibilities.  B. Nursing staff failed to clearly document wound care orders and implement preventative measures for patients at risk for skin breakdown and to prevent further skin breakdown for patients with wounds. (Patients #66 and 158)  C. Nursing staff failed to conduct assessments and measurements of wounds, per the facility's policy, to determine if current treatments were effective. (Patients #122, 159, 160, 161, and 162)	A 385			

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A 385	<p>Continued From page 177</p> <p>D. Nursing staff failed to prevent, identify, and assess avoidable pressure ulcers/injuries. (Patients # 306, 308, and 309)</p> <p>Cross Refer to Tag A0386</p> <p>Hospital # 2 failed to provide nursing staffing per policy for 1 of 21 hospital nursing units (Medical Intensive Care) for the time period of August 1-31,2019.</p> <p>Cross Refer to tag A0392</p> <p>Based on record review and interview, the facility failed to ensure training and competencies were current for nurses administering moderate sedation in 2 of 16 staff records reviewed (Staff # 102 and #276 ).</p> <p>This deficient practice had the likelihood to cause harm in all patients receiving moderate sedation for procedures in Hospital 1 and 2.</p> <p>Cross Refer to A0397</p> <p>Nursing staff failed to administer drugs according to acceptable standards of practice and professional guidelines.</p> <p>Registered Nursing staff at Hospital 1 and Hospital 2 failed to disinfect the rubber septum of medication vials prior to drawing up medication into a syringe.</p> <p>This deficient practice could lead to the contamination of the medication and cause harm</p>	A 385		

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A 385	<p>Continued From page 178 to the patients.</p> <p>Cross Refer to: A-405</p> <p>A. Nursing staff at Hospital 1 failed to ensure vital signs were assessed during and after blood transfusions in 3 of 9 (#120, 121, and 406) medical records reviewed for blood transfusions. Facility policy and nursing education for blood and blood product administration was incomplete with respect to vital signs monitoring during a potential or actual transfusion reaction and lacked definitions or parameters for monitoring reactions.</p> <p>B. Nursing staff at Hospital 2 failed to titrate (adjust dosage based on patient response to medication) intravenous (IV) medications per physician orders in 1 (Patient #239) of three patients observed who were currently receiving titratable IV medications.</p> <p>C. Hospital 2 failed to develop training material specific to objective indicators of blood transfusion reactions that the nursing staff should monitor for and report. Current training materials required nursing staff to use their own judgement as to whether or not a symptom was an indicator of blood transfusion reaction.</p> <p>Cross Refer to A-0409</p> <p>Based on observation, review of documentation, and interview, it was determined that nursing staff at Hospital 1 failed to ensure that patient home medications were secured.</p>	A 385			

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A 385	Continued From page 179	A 385			
A 386	<p>Cross Refer to A-0413</p> <p><b>ORGANIZATION OF NURSING SERVICES</b> CFR(s): 482.23(a)</p> <p>The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure a well-organized organized nursing service. The hospital failed to :</p> <p>A. Ensure that clear lines of authority had been established to show there was only one hospital-wide, unified nursing service. The organizational chart and job description for the Chief Nursing Officer (CNO) position showed that each campus location had a different CNO with lines of authority and designated responsibilities establishing independent nursing services rather than a hospital-wide, unified nursing service. No documents were provided that reflected clear lines of authority to only one Registered Nurse (RN) directing all of nursing services.</p> <p>B. Nursing staff failed to clearly document wound care orders and failed to ensure recommended preventative measures were being followed for</p>	A 386			

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A 386	<p>Continued From page 180</p> <p>patients at risk for skin breakdown and to prevent further skin breakdown for patients with wounds. (Patients #66 and 158).</p> <p>C. Nursing staff failed to conduct assessments and measurements of wounds, per the facility's policy, to determine if current treatments were effective. (Patients #122, 159, 160, 161, and 162).</p> <p>D. Nursing staff failed to prevent, identify, and assess avoidable pressure ulcers/injuries. (Patients # 306, 308, and 309)</p> <p>Findings:</p> <p>A. Unified Nursing Service: Hospital 1 and 2:</p> <p>This hospital is a multi-campus hospital, here in referred to as Hospital #1 and Hospital #2, with a single license and Medicare participation agreement. As a single hospital, nursing services should have been structured as a single nursing service with clear lines of administrative authority.</p> <p>Review of organizational charts and job descriptions showed that both campuses (Hospital #1 and Hospital #2) were operating with separate nursing services under the direction of an Associate Administrator/Chief Nursing Officer who reports directly to the hospital campus Executive Vice President/Administrator. The hospital campus EVP/Administrator reports directly to the hospital President/ Chief Executive Officer.</p>	A 386			

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A 386	Continued From page 181  During a review of the organizational chart for Hospital #2 on 9-16-2019, Nursing Departments were observed to have direct lines of reporting to the Associate Administrator/Chief Nursing Officer. The Associate Administrator/Chief Nursing Officer had direct lines of reporting to the Executive Vice President/Hospital 2 Administrator.  An interview was conducted with Staff #S329 and Staff #S330 on 9-17-2019 at Hospital #2 during a review of the Associate Administrator/Chief Nursing Officer's personnel file with job description and the organization chart. Staff #S329 and #S330 both confirmed that the Associate Administrator/Chief Nursing Officer at Hospital #2 directly reported to the Executive Vice President/Hospital 2 Administrator. The Executive Vice President/Hospital 2 Administrator was responsible for evaluating the performance of the Chief Nursing Officer (CNO) as evidenced by the most recent Annual Performance Review completed on 5/20/2019. Review of the Job Summary also showed that the CNO had a direct reporting structure to the Executive Vice President/Hospital 2 Administrator.  An interview was conducted with the CNO of Hospital #2 on 9-17-2019 at 2:20 PM, to determine the lines of authority. The CNO confirmed that he did not report to Hospital #1 and Hospital #1 did not report to him. Each CNO reported to their respective Hospital Administrator. Each CNO acted independently with their nursing staff. The CNO reported that when things came up that affected the Hospital	A 386			

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A 386	<p>Continued From page 182</p> <p>System, each CNO had a dotted-line reporting to the Senior Vice President/Chief Nursing Executive (CNE) and would take those issues to the System Nurse Executive Council which met regularly.</p> <p>The CNO job description stated, "The Chief Nurse Officer (CNO) is the executive leader responsible for implementing nursing's philosophy, vision, and strategic direction within the organization. The CNO is accountable for operational leadership, human resource management, financial control, and quality improvement for the nursing within his/her defined areas of responsibility." "The CNO reports through a matrix and has a direct reporting relationship to the Hospital Administrator/Executive Vice President, and an additional reporting relationship to the Chief Nursing Executive."</p> <p>B. Documentation of wound care orders &amp; implementation of skin breakdown preventative measures:</p> <p>Hospital 1:</p> <p>Review of the facility provided policy #431 PRESSURE INJURY PREVENTION AND TREATMENT (dated 09/2018) reflected, "Upon admission, skin assessment shall be completed by nursing and documented in the patient's medical record and reassessed every shift and during transfer of care between health care providers .... E. The pressure injury (ulcer) prevention plan shall include interventions that minimize or eliminate friction and sheer, minimize</p>	A 386			

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A 386	<p>Continued From page 183</p> <p>pressure with off-loading, manage moisture, and maintain adequate nutrition and hydration ... D. Upon identification of a wound, a full wound assessment, including its location, size, and description of the tissue involved, shall be completed ..."</p> <p>PATIENT #66</p> <p>Review of Patient #66's medical records revealed a 62-year-old male presented on 7/10/19 to the facility's emergency department. The admission photos show the sacral skin is intact.</p> <p>Review of the wound care nurse's notes reflected the following:</p> <p>On 7/12/2019 at 12:26 am</p> <p>Perianal: moisture related skin damage. Skin is moist, macerated, and erythematous. Periwound [sic]: clean, moist, intact.</p> <p>Odor: mild.</p> <p>Category 3- the skin flap is completely absent. Partial thickness skin loss. Wound bed with 100% red tissue. Edges are irregular, open, attached to base. Periwound: C/D/I. No drainage noted.</p> <p>Braden Score: 14 Level of Risk: H.</p> <p>ADDITIONAL RECOMMENDATIONS:</p> <p>1. Turn pt. Q2hr; avoid supine (lying on the back) position/pressure to wound. Turn left or right side. Use foam wedge for optimal offloading. Provide cushion to hips or apply</p>	A 386			



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A 386	<p>Continued From page 184 mepilex border dressing.</p> <p>Review of the Wound Care Nurse's assessments of the Sacral wound revealed the following:</p> <p>On 7/18/19, Wounds are measured by Length X Width X Depth (LxWxD) in centimeters.</p> <p>Sacrum: Pressure injury, DTI (deep tissue injury) Measurement: 6X4Xunable to determine, Intact skin with non-blanchable deep red, maroon, purple discoloration. Additional Recommendation. Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal offloading.</p> <p>On 8/1/19, Sacrum: Unstageable pressure injury. Measurements: 2X5.2Xunable to determine. Wound bed obscured by 45% yellow slough, 5% dark red tissue, and 50% dark tan discoloration to skin. Additional Recommendation. Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal offloading.</p> <p>On 8/8/19, Sacrum: Unstageable pressure injury. Measurements: 2.5X4Xunable to determine. Wound bed obscured by 90% white non-viable tissue and 10% dark red tissue. Additional Recommendation. Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal offloading.</p> <p>On 8/11/19 at 7 PM, the nurse's documented an unstageable sacral wound with excoriation. The nursing documentation did not include</p>	A 386			

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A 386	<p>Continued From page 185 measurements of the wounds.</p> <p>On 8/12/19, the wound care nurse assessed the wounds and wrote orders and recommendations to be followed.</p> <p>On 8/23/19, Sacrum: Unstageable pressure injury. Measurements: 3X3.8Xunable to determine. Additional Recommendation. Turn pt. Q 2hrs, turn left or right side and document: Avoid supine position/pressure to wound. Use foam wedge for optimal offloading.</p> <p>On 9/11/19, Sacrum: unstageable pressure injury. Wound measures 6.0cmLx6.0cmWx2.0cmD. Undermining noted from 9 o'clock to 5 o'clock. Deepest point at 12 o'clock of 1.2 cm. Wound base is 98% tan, tenacious nonviable tissue with 2% pale pink tissue. Edges are defined by not attached. Peri wound is denuded and macerated. Dressing that was removed was saturated with serosanguineous drainage. Additional Recommendation. Turn pt. Q 2hrs, Avoid supine position. Use foam wedge for optimal offloading.</p> <p>On 9/13/19 at 11:47 am, the wound care nurse writes an order for dressing changes but does not describe the location or the area to be changed.</p> <p>On 9/19/19 at 11:03 am, the wound care nurse writes an order for dressing changes but does not describe the location or the area to be changed.</p> <p>Review of Patient #66's turning and repositioning documentation revealed the following:</p> <p>7/12/19 at 2 am- Supine, 7 am- Supine, 11 am-</p>	A 386			

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A 386	Continued From page 186 Supine, from PM to 10 PM- no turning was documented.  7/13/19 at 8 am- Supine, 6 PM- Supine, 10 PM- Supine  7/14/19 at 2 am- Supine, from 6 PM to 6 am- no documented turning.  7/15/19 at 6 PM- Supine, 12 am- Supine, 4 am- Supine  7/17/19 at 8 am- Supine, 12 PM- Supine, 4 PM, no documented turning.  7/18/19 at 6 am- till 7/20/19 the patient was no documented turned, Veniflex, do not turn.  7/21/19 at 6 PM- Supine, 8 PM- Supine  7/22/19 at 8 PM- Supine  7/23/19 at 8 PM- Supine, 2 am- Supine  7/24/19 at 9 am-Supine, from 10 PM to 7 am- no documented turning  7/26/19 at 2 PM- Supine, from 10 PM to 7/27/19 at 6 am- Supine  7/27/19 at 12 PM- Supine  7/29/19 at 10 PM- Supine  7/30/19 at 2 am- Supine, 8 PM- Supine  7/31/19 at 12 am- Supine, 10 PM- Supine  8/1/19 at 2 am- Supine, 12 PM- Supine, 3:40 PM-	A 386			

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A 386	Continued From page 187 Supine, 6 PM- Supine, 8 PM- Supine, 10 PM- Supine, 10 PM- Supine  8/2/19 from 4 am to 6 PM- No documented turning  8/7/19 at 6 PM- Supine  8/9/19 at 12 am- No documented turning  8/15/19 from 11 am to 3 PM- no documented turning  8/16/19 at 11 am- no documented turning, from 7 PM 6:30 am- no documented turning  8/27/19 at 8:27 am- no documented turning, 12 PM- Supine, 8 PM- Supine  8/28/19 at 12 am- Supine, 4 am- Supine  8/31/19 at 2 PM- Supine  9/3/19 at 3 PM- Supine, 7:15 PM- Supine  9/5/19 from 9 PM to 1 am- no documented turning  9/6/19 at 4 PM to 7:15 PM- no documented turning  9/11/19 at 2 am- Supine  9/12/19 at 1 am- Supine, 2 am- Supine, 4 am- Supine, 5 am- Supine, 6 am- Supine, 7 PM- Supine, 9 PM- Supine, 10 PM- Supine  9/13/19 at 12 am- Supine	A 386			

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A 386	<p>Continued From page 188</p> <p>During an interview on the morning of 9/20/19, Staff #S401 confirmed the findings and stated Patient #66 was noncompliant and would place himself in the supine position. Staff #S401 was unable to provide documentation of Patient #66's noncompliance or the staffs re-educating the patient when Patient #66 was found in the Supine position.</p> <p>Review of Patient #66's treatment plan revealed the wound skin treatment plan was not added until 8/19/19 at 9:40 PM and was not updated to reflect Patient #66's continued non-compliance with lying supine and interventions to assist with compliance such as re-education and the use of wedges for positioning.</p> <p>PATIENT #158</p> <p>Review of Patient #158's medical records revealed an elderly patient admitted on 6/13/19.</p> <p>On 6/17/19, the wound care nurse documented, Buttocks, scar tissue.</p> <p>On 6/24/19, the wound care nurse documented, right/left only; 5cmX7cm with 34% external dermal.</p> <p>On 8/8/19, the wound care nurse documented, 9cmX11.5cm with 90% and 10% pink base.</p> <p>On 7/20/19, the nurse's note reflected a small skin tear to sacrum. The wound was not measured.</p> <p>On 7/22/19, the nurse's note reflected (2) sacral</p>	A 386		

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A 386	<p>Continued From page 189</p> <p>wounds, the wounds were not measured.</p> <p>On 7/29/19, the wound care nurse documented- 8.5cmX11.5cm with 100% adherent black neurotic tissue.</p> <p>Review of Patient #158's turning and repositioning documentation revealed the following:</p> <p>6/24/19 at 7 PM- Supine, 11:00 PM- Supine</p> <p>6/26/19 at 1:00 am- Supine</p> <p>6/28/19 at 2:30 PM- Supine</p> <p>6/29/19 at 11:00 PM- Supine</p> <p>6/30/19 at 3:00 am- Supine</p> <p>7/6/19 at 9:00 am- Semi fowlers (reclining on back side), 9:00 PM- Semi fowlers</p> <p>7/20/19 at 3:00 9m- Supine</p> <p>7/23/19 at 7:00 am- Semi fowlers</p> <p>7/24/19 at 7:00 am- Semi fowlers</p> <p>Review of the facility provided policy #431 PRESSURE INJURY PREVENTION AND TREATMENT (dated 09/2018) reflected, "Purpose: To outline a comprehensive regimen designed to prevent, identify, and manage pressure injury (ulcer); to provide the guidelines for identifying at-risk patient, and the specific factors placing them at risk for the development</p>	A 386			

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A 386	<p>Continued From page 190 of pressure injury (ulcer).</p> <p>Policy Statement: All inpatient of _____ Health System shall be assessed for pressure injury (ulcer) and the risk of its development. Appropriate standardized assessment tools shall be used to identify at-risk patients and specific modalities shall be utilized to prevent and treat pressure injury (ulcer).</p> <p>F. PRESSURE INJURY: A localized injury to the skin and/or underlying tissue usually over a bony prominence; the result of pressure or pressure in combination with shear and/ or friction."</p> <p>Review of the facility policy #4001 Wound Care (dated 03/03/2019) reflected, "Purpose: to establish patient care guidelines to be used when a wound care referral is received by _____ Health System Physical Therapy ... Procedure for Inpatient Referrals: 1. WOCNURSE will assess all consults regarding pressure ulcers, moisture management ..."</p> <p>C) Assessments &amp; measurements of wounds :</p> <p>Review of the facility policy (Undated) staff training, "_____ HEALTH SKIN CARE MODULES Module 2: Pressure Injury Staging ... WOUND MEASUREMENTS, Wounds are measured by Length X Width X Depth (LxWxD). This is the diameter from edge to edge of wound. Any tunneling/undermining must be measured and identified.</p>	A 386			

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A 386	<p>Continued From page 191</p> <p>PATIENT #161</p> <p>Review of Patient # 161's medical records reflected a 72-year-old-female admitted on 7/14/19 with a diagnosis of NSTMI (non-ST elevation myocardial incident)</p> <p>On 7/16/19, the nurse documented a skin tear to buttock. The nursing documentation did not include measurements of the wounds.</p> <p>On 7/17/19, the wound care nurse recorded the following: Lower back: Suggest pressure injury DTI (deep tissue injury). Measurements (LXWXD) (cm) 4x3.5x unable to determine. Buttocks skin fold: Moisture related skin damage. Measurements (LXWXD) (cm) 3x0.3x0.23.5x unable to determine</p> <p>On 7/17/19, a medial midline bruise. The nursing documentation did not include measurements of the wounds.</p> <p>On 7/10/19, an excoriation below breast. The nursing documentation did not include measurements of the wounds.</p> <p>On 7/22/19, fluid filled blister. The nursing documentation did not include measurements of the wounds.</p> <p>During an interview on the morning of 9/25/19, in the facility conference room, Staff #S546, confirmed the findings and stated, "The measurements are not there..."</p> <p>PATIENT #122</p>	A 386			



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A 386	<p>Continued From page 192</p> <p>Review of Patient #122's medical records revealed a 45-year-old-female with an open wound to RLE s/p debridement's for necrotizing fasciitis.</p> <p>The Physical Therapy Wound Care Evaluation dated 9/13/19 reflected the following: Dressing change by nursing: Frequency daily. Clean the wound with gauze moistened with dermal wound cleanser ... Wound Size (cm): L: 25.0cm W: 10.5cm D: 0.8cm</p> <p>Review of the nurses wound care and assessment notes dated 9/25/19, reflected the dressing was changed by the night shift, the nurse did not document the wounds size, width or depth.</p> <p>Patient#162</p> <p>Review of Patient #162's medical records revealed a 50-year-old-male admitted on 8/12/19 with Sezary Syndrome, a skin condition that places the skin at risk of developing rashes. Patient #162 developed 3 wounds to the scalp, due to the EEG monitor lead placements.</p> <p>On 8/22/19, Patient #162 developed a wound to the left ear. The scalp wounds and the ear wound were not clearly described or measured.</p> <p>PATIENT #159</p> <p>Review of Patient #159's medical records reflected a 61-year-old-female admitted on 8/14/19 with a sacral decubitus ulcer and left foot</p>	A 386			

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A 386	<p>Continued From page 193 gangrene.</p> <p>On 8/16/19, the nurse documented a Stage 4 pressure wound; the nurse did not document the measurements or a description of the wound.</p> <p>On 8/16/19, the wound care nurse documented the wound at 6.5cmX5cmX4cm.</p> <p>PATIENT#160</p> <p>Review of Patient #160's medical records reflected a 64-year-old-male admitted on 6/26/19 with End Stage Renal Disease.</p> <p>On 6/26/19, the nurse documented- Skin intact.</p> <p>On 7/8/19, the nurse documented- right elbow, red swollen.</p> <p>On 7/10/19, the nurse documented- Left foot injury.</p> <p>On 7/11/19, the nurse documented- Rectum Skin tear, moisture related.</p> <p>On 7/11/19, the wound care nurse document, denuded, excoriated rectum.</p> <p>During an interview on the morning of 9/20/19, when asked if the wounds should be measured, Staff #150 stated, "Per policy, yes" and confirmed the findings.</p> <p>During an interview on the morning of 9/25/19, in the facility conference room, Staff #S399, "Once</p>	A 386			

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A 386	<p>Continued From page 194</p> <p>the wound is discovered the nurses are to remeasure the wound every Wednesday, if it hasn't improved by 0.2cm they have to put in a wound care nurse consult ... All wounds should be measured on admission by the nurses."</p> <p>D. Prevention, identification, and assessment of avoidable pressure ulcers/injuries:</p> <p>Hospital 1:</p> <p>Review of ____ Health System Pressure Injury Prevention and Treatment policy revised 08/2018 stated the following:</p> <p>" ....Upon admission, skin assessment shall be completed by nursing and documented in the patient's medical record and reassessed every shift and during transfer of care between health care providers .... E. The pressure injury (ulcer) prevention plan shall include interventions that minimize or eliminate friction and sheer, minimize pressure with off-loading, manage moisture, and maintain adequate nutrition and hydration ... D. Upon identification of a wound, a full wound assessment, including its location, size, and description of the tissue involved, shall be completed ..."</p> <p>Patient #306:</p> <p>Patient 306 was admitted 05/22/2019 with diagnoses of spinal stenosis and complaints of weakness to lower extremities. The patient had a spinal fusion surgery during hospitalization. A head to toe skin assessment was completed by 2 Registered Nurses on 05/22/2019 and no</p>	A 386			

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A 386	<p>Continued From page 195</p> <p>pressure injuries were identified. The Braden Scale, which is used to predict pressure ulcer risk was completed and patient 306 was at moderate risk for developing a pressure ulcer/injury. There was no nursing or provider documentation of any skin impairment until 06/18/2019.</p> <p>The first wound assessment for sacrum was documented 06/18/2019. Site assessment described wound as "Thinly crack on the mid of the sacrum) developed from an old scar {sic}"</p> <p>The first wound assessment for left heel was documented 06/17/2019 by nursing. Site assessment described wound as a deep tissue injury and was not present on hospital admission. This was the only wound that was identified.</p> <p>A WOCN consult was ordered 06/18/2019 by staff 743.</p> <p>A WOCN consult was completed and documented 06/18/2019 by staff 744. An unstageable pressure injury to the sacrum was identified (full thickness tissue loss in which the base of the ulcer is covered by slough {dead tissue separating from the pressure ulcer} and/or eschar {dead tissue that sheds or falls off from healthy skin}. Until enough slough and/or eschar is removed to expose the base of the wound, the depth, and staging of ulcer cannot be established). And a deep tissue injury (a pressure related injury to subcutaneous tissues under unbroken skin) to the left heel was identified. Wound care recommendations were given and the patient's primary provider team was notified of wound care recommendations.</p> <p>Records review showed there was no nursing</p>	A 386		

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A 386	<p>Continued From page 196</p> <p>care plan related to pressure ulcer/pressure injury prevention or care and there was little documentation of patient repositioning every two hours.</p> <p>Patient # 309:</p> <p>Patient 309 was admitted 05/26/2019 with diagnoses of left lower extremity gangrene, sepsis, and complaints of left foot pain. The patient underwent a left below the knee amputation 05/26/2019. A head to toe skin assessment was completed by 2 Registered Nurses on 05/22/2019 and no pressure injuries were identified. The Braden Scale, which is used to predict pressure ulcer risk, was completed and patient 309 was at a high risk for developing a pressure ulcer/injury. Skin assessments were ordered by Physician 747 on 05/26/2019.</p> <p>There was no nursing or provider documentation of any skin impairment until 06/05/2019</p> <p>The first wound assessment of buttock was completed 06/05/2019 by nursing. Site assessment described wound as "dark skin discoloration on left buttocks." A WOCN consult order was ordered 06/06/2019 by staff 745</p> <p>A WOCN consult was completed and documented 06/07/2019. A deep tissue injury with some exposed dermal tissue was identified. Wound care recommendations were given and the patient's primary provider team was called by WOCN per records review.</p> <p>On 06/12/2019 a WOCN assessment was completed. The buttock was staged as an</p>	A 386			

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A 386	<p>Continued From page 197</p> <p>unstageable with pink healthy tissue and yellow slough present. WOCN gave additional recommendations including repositioning every two hours, providing supplies to patient for discharge, and following up with a wound care clinic after discharge.</p> <p>Nursing care plan included:</p> <p>"Problem: Impaired Mobility ....Goal: The Maximum Level of Function Will Be Achieved And the Risk of Complications Reduced ....."Intervention: Monitor Skin Integrity",</p> <p>"Problem: Impaired Skin Integrity ...Goal: The Skin Will Remain Intact" ....Intervention: Assess Skin Daily For Impaired Integrity: Irritated, Reddened, Dry, Cracked Areas, Excoriation or Complaints of Itching .....Intervention: Assess All Breakdowns for Color, Size, Drainage, And Odor .....Intervention: Administer Medication, Treatments And Therapies Related To Wound Management And Prevention"</p> <p>All problems, goals, and interventions had a start date of 05/26/2019 and end date of 06/12/2019. Records review disclosed the patient was documented as a "self turn" and in a supine semi-fowlers position only.</p> <p>Patient 309 was discharged with wound care and follow up with an outpatient clinic.</p> <p>Patient # 308:</p> <p>Patient 308 was admitted 05/29/2019 with diagnoses of left hip fracture, uncontrolled diabetes mellitus, neuropathy, and hypertension.</p>	A 386			

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A 386	<p>Continued From page 198</p> <p>Patient 308 had a left hip repair surgery during hospitalization. A head to toe skin assessment was completed by 1 Registered Nurse and 1 Patient Care Assistant on 05/29/2019. No pressure injuries was identified. The Braden Scale, which is used to predict pressure ulcer risk, was completed. Patient 308 was at a high risk for developing a pressure ulcer/pressure injury.</p> <p>There was no nursing or provider documentation of any skin impairment until 06/03/2019.</p> <p>The first wound assessment was documented on 06/03/2019 by nursing. Site assessment described the wound as a "Skin tear Coccyx DTI". Wound type was documented as a "skin tear", wound description was documented as a "DTI" or deep tissue injury.</p> <p>A wound care consult was ordered 06/06/2019 by staff 746. A WOCN consult was completed and documented 06/07/2019 by staff 744. A deep tissue injury to the sacrum was identified. In addition, a deep tissue injury to the left hip was identified. Wound care recommendations were given and the patient's provider team was notified.</p> <p>Nursing care plan included:</p> <p>"Problem: Impaired Mobility .....Goal: The Maximum Level Of Function Will Be Achieved And Risk Of Complications Reduced ....Interventions: Monitor Skin Integrity....Intervention: Reposition As Needed ...."</p> <p>"Problem: Impaired Skin Integrity .... Goal: The</p>	A 386			

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A 386	Continued From page 199 Skin Will Remain Intact ....Intervention: Assess Skin Daily For Impaired Integrity: Irritated, Reddened, Dry, Cracked Areas, Excoriation Or Complaints of Itching ....Intervention: Assess All Breakdowns For Color, Size, Drainage, And Odor .... Interventions: Administer Medications, Treatments, And Therapies Related To Wound Management And Prevention ...."  All problems, goals and interventions were active 05/30/2019- 06/08/2019. Records review revealed the patient was documented as a self-turn post-surgery and noted to have decreased functional independence.  Patient 308 was discharged to an acute rehabilitation facility.  During an interview on 09/25/19, Staff #S399, stated, "Once the wound is discovered the nurses are to remeasure the wound every Wednesday, if it hasn't improved by 0.2cm they have to put in a wound care nurse consult.	A 386			
A 392	STAFFING AND DELIVERY OF CARE CFR(s): 482.23(b)  The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.  This STANDARD is not met as evidenced by: Based on interview, record review, and	A 392			



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A 392	<p>Continued From page 200</p> <p>observation , Hospital 2 failed to provide adequate numbers of nurses to provide care for all patients.</p> <p>Hospital # 2 failed to follow its staffing plan on 1 of 21 (Medical Intensive Care) hospital unit.</p> <p>Findings:</p> <p>Review of facility policy titled "Nurse Staffing" effective 10/29/09 and revised on 01/23/18 reflected ..."_____Health (system) shall: A. Implement and enforce a nurse staffing policy that ensures an adequate number and skill mix of nurses to meet the levels of care needed to provide safe quality patient care; B. Implement and enforce an official nurse-staffing plan that is based on the needs of each patient care unit and shift; and evidence relating to patient care needs ..."</p> <p>Nursing staffing sheets for the 21 nursing units for the time period of August 1-31, 2019 were reviewed.</p> <p>Record review of the Medical Intensive Care Unit (MICU) staffing sheets reflected:</p> <p>On 08/08/19, on the day shift and the night shift there were 14 patients; 2 Nurses had a 3:1 patient load.</p> <p>On 08/09/19 on the day shift there were 13 patients; 1 nurse was carrying a 3:1 patient load.</p> <p>On 08/09/19 on the night shift there were 13</p>	A 392			

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A 392	Continued From page 201 Patients; 1 nurse was carrying a 3:1 patient load. At 0430 1 nurse was pulled to another unit to sit with a psychiatric patient leaving 2 more nurses to carry a 3:1 patient load for the remainder of their shift.  On 08/11/19 on the day shift and the night shift there were 13 patients; 1 nurse was carrying a 3:1 patient load.  On 08/12/19 on the night shift there were 14 patients; 2 nurses were carrying a 3:1 patient load.  On 08/13/19 on the day shift there were 13 patients; 3 nurses were carrying a 3:1 patient load.  On 08/17/19 on the day shift there were 11 patients; 1 nurse was carrying a 3:1 patient load.  During a tour of the MICU on 09/17/19 at 1345, Staff RN #S95 stated, the staffing for the unit was 2 patients to 1 nurse.	A 392			
A 405	ADMINISTRATIONS 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	A 405			

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A 405	<p>Continued From page 202</p> <p>practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</p> <p>(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of documentation, and interviews with facility staff, the facility failed to ensure drugs were administered according to acceptable standards of practice and professional guidelines.</p> <p>Staff #S109 [Hospital 1] and Staff #S702 [Hospital 2] failed to disinfect the rubber septum of medication vials prior to drawing up medication into a syringe.</p> <p>This deficient practice could cause the contamination of the medication. Facility policies provided did not specify how the injectable medication vial septum should be disinfected.</p> <p>Findings:</p> <p>Hospital 1:</p> <p>During observation of a percutaneous nephrostomy tube placement in hospital #1 interventional radiology on 9/17/19 at approximately 10:15 am, Staff #S109 while drawing up fentanyl and versed removed the dust</p>	A 405			

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A 405	<p>Continued From page 203 covers from the vials and did not disinfect the rubber septums of the vials before drawing up the medications into syringes.</p> <p>In an interview with staff #S109 during the procedure on 9/17/19 at approximately 10:30 am, staff #S109 acknowledged these findings. In an interview with MRT supervisor, staff #S111 on 9/17/19 at approximately 11:30 am, the above finding was acknowledged.</p> <p>Institute for Safe Medication Practices (ISMP) Safe Practice Guidelines for Adult IV Push Medications publication reflected in part, "the 'pop-off' vial caps from manufacturers are considered 'dust covers' and are not intended to maintain sterility of the vial diaphragm or access point. Thus, the diaphragm must always be disinfected after removing the cap of a new vial."</p> <p>The facility policy entitled "Medication Administration" #565.00 dated 1/04 reflected in part, "Medication from each vial shall be administered using aseptic techniques." The facility document entitled "Procedural Support - Interventional Radiology: Registered Nurse: dated 1/13 reflected in part "Follows strict aseptic technique and standard precautions for all infusion procedures." Hospital # 2</p> <p>Observation on 09-24-19 at 8:15 A.M. showed Staff #S702 prepared to administer medication to Patient # 403.</p> <p>Review of physician order for Patient #403, dated 9-24-19, showed an order for Lasix 80 milligrams</p>	A 405			

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A 405	Continued From page 204 (mg) IVP (intravenous push) daily.  Continued observation showed staff #S702 removed two(2) vials of Lasix from her medication cart. Staff #S702 uncapped each vial and correctly withdrew a total of 8 milliliters (ml) into a single syringe. [Review of the Lasix medication label showed 1 ml=10 mg].  Staff #S702 failed to disinfect the rubber septum of either of the vials of Lasix.  During an interview on 09-25-19 at 10 A.M. with Staff #S495 she stated the medication vials should be swabbed with alcohol after the cap was removed & prior to use.  Review of Centers for Disease Control (CDC) Guidelines for Injection Safety, June 2019, showed:"Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it."	A 405			
A 409	BLOOD TRANSFUSIONS AND IV MEDICATIONS CFR(s): 482.23(c)(4)  Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by	A 409			

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A 409	<p>Continued From page 205</p> <p>personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review:</p> <p>A. Hospital # 1 failed to ensure :</p> <p>vital signs were assessed during and after blood transfusions in 3 of 9 (#120, 121, and 406) charts reviewed for blood transfusions. Facility policy and nursing education for blood and blood product administration was incomplete, without a requirement to monitor vital signs during a potential or actual transfusion reaction, definitions, or parameters for monitoring reactions. These deficient practices could potentially cause harm in all patients receiving blood products in the hospital.</p> <p>B. Hospital #2 failed to ensure:</p> <p>1. nursing staff who were titrating (adjusting dosages based on patient response to the medication given) Intravenous (IV) medications per physician orders to achieve the physician-ordered goal in 1 (Patient #239) of three patients observed who were currently receiving titratable IV medications;</p> <p>2. training material was developed and nursing staff were educated on specific, objective indicators of blood transfusion reactions that the nursing staff should monitor for and report. Education material contained subjective indicators that required nursing staff to use their</p>	A 409			

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A 409	<p>Continued From page 206</p> <p>own judgement as to whether or not a symptom was an indicator of blood transfusion reaction.</p> <p>Findings:</p> <p>A. Hospital 1: blood transfusion issues - vital signs &amp; policy/nursing training:</p> <p>Facility policy, "Administration of Blood and Blood Components and Blood Derivatives," last reviewed 5/31/2019, was provided to the survey team. The policy stated in part, "Appendix A Administration of Blood and Blood Components and Blood Derivatives ...</p> <p>II. Administration of Blood/Blood Components: ...</p> <p>3. Measures and records baseline vital signs, within 15 mins prior to the procedure to include:</p> <p>A. Temperature</p> <p>B. Blood pressure</p> <p>C. Pulse</p> <p>D. Respirations ...</p> <p>10. Observes patient closely during the first fifteen minutes. Obtain and document a set of vitals at the 15 minutes mark after the start of the infusion.</p> <p>11. If signs/symptoms of transfusion reaction are noted at any time during the transfusion, immediately stop the transfusion and follow the Transfusion reaction protocol.</p>	A 409			

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A 409	<p>Continued From page 207</p> <p>12. Measures and documents</p> <p>a. Vitals prior to infusion</p> <p>b. Vitals 15 minutes after the start of the infusion</p> <p>c. Vital signs every hour until completion</p> <p>d. Vital signs upon completion of administration ...</p> <p>II. Transfusion Reaction Procedure:</p> <p>If signs/symptoms of transfusion reaction are noted at any time during the transfusion, immediately stop the transfusion and</p> <p>a. Notifies the physician and blood bank</p> <p>b. Administer medications/treatments as ordered</p> <p>c. Physician to order the Transfusion Reaction Protocol which includes</p> <p>-a. Collect one pink top tube of patients' blood and a urine specimen which is the 1st post transfusion being started.</p> <p>-b. Sends collected specimens and un-transfused portion of blood component with attached tubing and IV fluid to blood bank.</p> <p>d. Leave the IV site intact or maintain IV"</p> <p>In an interview conducted in Hospital (1) conference room at 1:20 PM on 9/23/19 with Staff #S311, the above policy was reviewed. Staff #S311 confirmed that the "Administration of Blood</p>	A 409			



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A 409	<p>Continued From page 208</p> <p>and Blood Components and Blood Derivatives" policy did not define signs and symptoms of a transfusion reaction, such as back pain, chills, flushing, shortness of breath, itching, changes in temperature, blood pressure, pulse, or oxygen saturation, anaphylaxis, or cardiac arrest. Staff #S311 also confirmed that the facility policy did not require monitoring of vital signs or indicate the frequency of monitoring vital signs if a transfusion reaction is suspected.</p> <p>Review of the Nursing Education slide presentation document entitled, "Blood Administration (and Transfusion Reactions) updated August 2019, listed potential transfusion reaction signs and symptoms of fever, high fever, hypotension, severe hypotension, and sudden severe hypotension. However, fever, high fever, hypotension, severe hypotension, and sudden severe hypotension were not defined and parameters were not given. The training stated, "If a transfusion reaction is suspected, rapidly perform the following interventions ...Monitor the patients vital signs every 15 minutes or as indicated." Staff #S311 confirmed the above findings in the nursing education for blood administration and transfusion reactions.</p> <p>Review of patients who received blood or blood components transfusion:</p> <p>Patient #120</p> <p>The record for Patient #120 was reviewed on 7/20/19 with Staff #S48 and #S148. Patient #120 had an order for 1 unit red blood cells on 8/15/19 at 11:00 am.</p>	A 409			

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A 409	<p>Continued From page 209</p> <p>At 12:00 - Temperature 99 F, Blood pressure 135/89, Pulse 106, Respirations 25.</p> <p>At 12:09 - Pretransfusion documentation completed.</p> <p>At 12:11 - Transfusion initiated.</p> <p>At 12:29 - Temperature 100 F, Blood pressure 135/83, Pulse 89, Respirations 18.</p> <p>At 13:24 - Temperature 99.9 F, Blood pressure 148/74, Pulse 86, Respirations 18.</p> <p>At 13:34 - transfusion stopped.</p> <p>At 14:31 - Temperature 101.8 F, Blood pressure 140/84, Pulse 106, Respirations 20.</p> <p>At 15:23 - Temperature 99.3 F, Blood pressure 121/77, Pulse 110, Respirations 17.</p> <p>Vital signs were not monitored for 52 minutes after the last vital signs documented at 13:24 when the decision was made to stop the transfusion for a potential transfusion reaction with vital sign changes. The transfusion reaction protocol was initiated. There was no documentation of monitoring until the next vital signs were obtained at 14:31. This was confirmed during an interview while reviewing the patient record with Staff #S148.</p> <p>Patient #121</p> <p>The record for Patient #121 was reviewed on the</p>	A 409			

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A 409	<p>Continued From page 210</p> <p>afternoon of 9/20/19 in the conference room with Staff #S237 and #S303. Patient #121 had an order for 2 units of red blood cells on 7/17/19 at 5:46 PM. The patient experienced a transfusion reaction during the second unit on 7/18/19.</p> <p>At 0005 - Temperature 98.7 F, Blood pressure 121/61, Pulse 96, Respirations 18</p> <p>At 0008 - Transfusion started.</p> <p>At 0025 - Temperature 98.7, Blood pressure 130/59, Pulse 98, Respiration 18</p> <p>At 0050 - Temperature 98.6, Blood pressure 128/56, Pulse 98, Respirations 18</p> <p>At 0120 - Temperature 101.5, Blood pressure 129/61, Pulse 102, Respirations 20 Transfusion stopped.</p> <p>At 0205 - Temperature 99.6, Blood pressure 129/61, Pulse 102, Respirations 22</p> <p>At 0300 - Temperature 99, Blood pressure 118/57, Pulse 98, Respirations 21</p> <p>Vital signs were not monitored every 15 minutes after possible transfusion reaction with no documentation of indication for vital signs less than 15 minutes. This was confirmed in an interview with Staff #S237 and S303 while reviewing the medical record.</p> <p>Another unit of red blood cells was started on 7/19/19 at 1237.</p>	A 409			

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A 409	<p>Continued From page 211</p> <p>At 12:11 - Temperature 98.5, Blood pressure 118/64, Pulse 94, Respiration 16.</p> <p>At 12:35 - Temperature 98.6. No blood pressure, pulse, or respirations documented.</p> <p>At 12:39 - Transfusion started.</p> <p>At 12:52 - Temperature 100 F, Blood pressure 106/53, Pulse 93, Respirations 16</p> <p>A complete set of vital signs, including blood pressure, pulse, or respirations, was not obtained per policy within 15 minutes prior to starting the transfusion at 12:39 PM. This was confirmed in an interview with Staff #S237 and S303 while reviewing the medical record the afternoon of 9/20/19 in the conference room.</p> <p>Patient #406</p> <p>The record for Patient #406 was reviewed the afternoon of 9/23/19 in the facility conference room with Staff #S303. Patient #406 had an order for 1 unit of FFP (fresh frozen plasma) on 7/23/19 at 4:30 PM.</p> <p>At 16:31 - Temperature 97.5, Blood pressure 123/65, Pulse 71, Respirations 16</p> <p>At 16:43 - Temperature 98.1, Blood pressure 109/57, Pulse 69, Respirations 14. Transfusion started</p> <p>At 1658 - Temperature 98.1, Blood pressure 110/58, Pulse 71, Respirations 14</p>	A 409			

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A 409	Continued From page 212 At 1700 - Temperature 98.1, Pulse 70, Respirations 14. Blood pressure not documented.  At 1713 - Pulse 68, Respirations 14  At 1715 - Pulse 69, Respirations 14  At 1718 - Pulse 69, Respirations 14  At 1720 - Pulse 14  At 1730 - Pulse 68, Respirations 14  At 1743 - Temperature 98.1, Blood pressure 128/64, Pulse 69 Respirations 14  At 1745 - Pulse 68, Respirations 14  At 1758 - Temperature 97.7. Blood pressure, Pulse, Respirations not documented.  At 1800 - Temperature 97.5, Pulse 66, Respirations 14  At 1815 - Transfusion stopped Temperature 97.5, Pulse 67, Respirations 14 - Blood pressure not documented.  At 1830 - Pulse 65, Respirations 14  At 1845 - Pulse 68, Respirations 16. Blood pressure, Pulse, Respirations not documented.  At 1900 - Temperature 98.6, Pulse 65, Respirations 17. Blood pressure not documented.  At 1915 - Blood pressure 139/79, Pulse 100, Respirations 22	A 409			

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A 409	Continued From page 213  Vital signs for the transfusion were not taken per policy. A complete set of vital signs, including temperature, blood pressure, pulse, or respirations, was not obtained per policy within 15 minutes prior to starting the transfusion at 1643. After the transfusion was initiated, the vital signs were not taken per policy, including a complete set of vital signs every hour until completion and a set of vital signs upon completion of administration (there was no blood pressure documented on completion of the transfusion). There was no blood pressure documented between 1743 and 1915.  A "Hospital (1) Blood Bank Blood Pressure Infusion Record" form was provided to the surveyor for the above transfusion for Patient #406. Vital signs were documented for the patient on the blood bank form which were not documented in the medical record, including a complete set of vital signs at 17:13, 17:58, and 18:15. However, the form is not a part of the medical record.  The above findings were confirmed in an interview with Staff #S303 while reviewing the medical record the afternoon of 9/23/19 in Hospital (1) conference room.  B. Hospital 2:  1. Incorrect titration of IV medication:  On the morning of 9-26-2019, a tour of the Medical Intensive Care Unit (MICU) at Hospital #2 was made. Staff #S705 was observed titrating norepinephrine (a medication used to increase	A 409		

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NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 409	<p>Continued From page 214</p> <p>blood pressure) for Patient #239. Staff #S705 explained that she was increasing the rate of infusion by 2 micrograms per minute (mcg/min) in order to achieve a MAP greater than 65 (mean arterial pressure - based off a calculation using blood pressure readings. MAP is used to help determine how well vital organs are receiving adequate blood flow). The MAP was being calculated and monitored for Patient #S239 through an arterial line (ART line), which was a thin catheter inserted into an artery.</p> <p>Review of literature on the National Institute of Health website, <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355573/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355573/</a>, explained the following about the MAP, "Prolonged hypotension, defined as a MAP of less than 60 to 65 mm Hg, is associated with poor outcome".</p> <p>Review of documentation in the electronic patient record showed that the medication was started at 1 mcg/min at 9:10 AM on 9-26-2019 per physician order. Between 9:10 AM and 9:20 AM, the medication had been titrated up to 8 mcg/min with a blood pressure of 77/45 and a MAP of 56 at 9:20 AM. The next increase of medication was made 40 minutes later, at 10:00 AM. Review of the ART line readings showed that the MAP had never achieved the ordered target of greater than 65 between the time it was started and the time the increases began again at 10:00 AM. Nineteen (19) potential rate changes necessary to achieve the ordered MAP of greater than 65 were missed during that 40-minute time period.</p>	A 409			

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A 409	<p>Continued From page 215</p> <p>An interview was conducted with Staff #S705 was conducted at the patient's bedside on 9-26-2019 after 11:00 AM. Staff #S705 confirmed that she was assigned two patients and had been providing patient care to her second patient during the 40-minute time gap.</p> <p>An interview was conducted on 9-26-2019 after 11:00 AM with Staff #S94. Staff #S94 stated, she was on the other end of the unit and didn't know that Staff #S705 needed assistance with her patient. Staff #S94 confirmed that there is not an automatic process to place a patient on a 1:1 (one patient to one nurse) when they had critical and frequent medication titration changes necessary, until the desired goal was achieved and the patient acuity returned to a level that 1 nurse could then manage 2 patients again.</p> <p>Because there was not an automatic process, this placed the burden on the nurse who was assigned two patients and trying to manage one with frequent medication changes to ask other nursing staff for assistance. This process could create a situation where the nurse may not be able to locate other staff in her area because they are caring for their assigned patients, forcing her to leave the patient needing frequent titrations to tend to her other patient assigned or delay care to her other assigned patient.</p> <p>2. Non-specific policy &amp; education related to blood transfusion reaction /patient monitoring:</p> <p>On 9-25-2019 at 10:00 AM, personnel files for nursing staff were reviewed at Hospital #2. The</p>	A 409			



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A 409	<p>Continued From page 216</p> <p>staff were found to have specialized training in blood transfusion. The module content for blood transfusion reaction training was requested for review. Review of the content showed that symptoms to be monitored for were listed in vague, subjective terms. Terms included: fever, high fever, hypotension, severe hypotension, sudden severe hypotension, severe nausea and vomiting, severe chills, and hypertension. No parameters or definitions of these terms were listed. Without clear parameters and definitions to define these terms, nurses had to make their own decision of what the parameters would be, such as what qualified as severe and if a patient's normal blood pressure qualified as the medical definition of hypertension or hypotension, when should it be identified as a reportable transfusion reaction and when does it become severe.</p> <p>Review of Policy Number 4170 Administration of Blood Components and Blood Derivatives did not explain what the parameters or definitions for transfusion reaction signs and symptoms were.</p> <p>Staff #S415 at Hospital #2 Outpatient Infusion Center was asked about the terms, how they were defined and when they would be reported. Staff #S415 stated it would depend on the patient and what was going on with them. Staff #S415 was not able to explain an objective process for qualifying the subjective terms used to describe a transfusion reaction.</p> <p>Without objectively defined transfusion reaction signs and symptoms, the nursing staff was relying on their own judgement and could potentially miss a life-threatening blood transfusion reaction.</p>	A 409			

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A 413	<p><b>SELF-ADMINISTRATION - DRUGS FROM HOME</b> CFR(s): 482.23(c)(6)(ii)</p> <p>[The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.]</p> <p>(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:</p> <p>(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.</p> <p>(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).</p> <p>(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.</p> <p>(D) Address the security of the medication(s) for each patient.</p> <p>(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of documentation,</p>	A 413			

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A 413	<p>Continued From page 218</p> <p>and interview, it was determined that Hospital 1 failed to ensure that patient's home medications were secured.</p> <p>Findings:</p> <p>Hospital 1:</p> <p>Patient home medications were not secured. During a tour of Hospital 1, 5F nursing unit on the afternoon of 9/17/2019, the surveyor observed that in room 7 there were unsecured patient's home medications. When the surveyor entered the patient's room, accompanied by staff member #S64 and staff member #S132, the patient was not in the room.</p> <p>On the window ledge there was a small, shaving kit type bag that was open and it was observed to contain unsecured pill bottles. The pill bottles were taken to the nurse's station by the nurse manager and an examination of them revealed that there were 4 separate bottles all labeled with the name of patient #125. One of the bottles was labeled Tramadol 50 milligram (mg) mg and was observed to contain one tablet. Another bottle was labeled Lisinopril/HCTZ 20/25 mg and was observed to contain approximately 7 tablets. Another bottle was labeled Promethazine 25 mg and was observed to contain approximately 7 tablets. The last bottle was labeled Lisinopril/HCTZ 20/25 mg and was observed to contain approximately 20 tablets (note: staff member #S132 confirmed that there were approximately 20 tablets in the pill bottle).</p> <p>The surveyor asked staff member #S64 if there was a physician's order for this patient to have home medications at the bedside. Staff member</p>	A 413			

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A 413	<p>Continued From page 219</p> <p>#S64 checked the electronic medical record and confirmed that there was no such order. Additionally, staff member #S64 checked the electronic medical record and informed the surveyor that the patient was not on any of these unsecured medications.</p> <p>Staff member #S64 also informed the surveyor that the medications that were found in the patient's room should not be at the bedside. Staff member #S64 added that these medications had just been brought in today by a friend of the patient.</p> <p>Review of hospital policy #521.00, entitled "Patient Medications Brought From Home" with a last revised date of 04/09/2019 stated, "To assure patient safety in the handling of medication(s) or remedy(ies) brought from home by or for a patient admitted to a _____ Health System facility for an inpatient stay."</p> <p>The policy also stated: "____ Health System shall safely handle and monitor use of medication(s) or remedy(ies) brought from home by or for a patient admitted as an inpatient to a Harris Health System facility."</p> <p>Review of hospital policy #565.00, entitled "Medication Administration" with an effective date of 10/1/2004 stated, "To establish the guidelines for the safe and accurate administration of medications within approved areas of ____ Health System facilities." The Policy stated, "It is the policy of ____ Health System, through the implementation of the measures outlined, to enhance accuracy during medication</p>	A 413			

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A 413	<p>Continued From page 220 administration and enhance patient safety."</p> <p>In the definitions section of the policy: "C. Bedside Medications: Medications stored within the patient's immediate vicinity for which the patient has ready access for use while hospitalized."</p> <p>"L. Qualified Licensed Personnel (QLP): Any individual permitted by law and by Harris Health to provide care and services, without relevant direction or supervision with the scope of the individual's license and consistent with individually granted clinical privileges."</p> <p>"P. Security of Medications: For the purposes of this policy, security of the storage area for medications is defined as "under the constant surveillance of authorized users or secured within a locked device, cabinet, or room where only authorized personnel have access."</p> <p>Page 10 of the policy stated under: "VIII. Bedside Medications: A. Orders for medications to be stored at the bedside shall be written by QLP. The order shall contain all necessary components of a medication order as well as a statement specifying that the medication shall be stored at the bedside."</p> <p>"E. Medications left at the bedside shall be maintained in a secure area."</p> <p>"G. Medications left at the bedside shall follow general labeling guidelines (Medication Use Safety Policy 564.40 Medication Storage, Labeling and Disposal) and be limited to as needed (PRN) medication is the following categories: 1. Hemorrhoidal preparations (e.g.</p>	A 413			

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A 413	Continued From page 221 with hazel pads, hydrocortisone creams or ointments); 2. Topical lotions, creams or ointments used as a comfort measure and not treatment; 3. Oral care regimens; 4. Lubricant eye drops; and/or 5. Saline nasal drops or sprays."	A 413		
A 492	PHARMACIST RESPONSIBILITIES CFR(s): 482.25(a)(1)  [§482.25 Condition of Participation: Pharmaceutical Services The hospital.... must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision....  §482.25(a)(1) - A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. This STANDARD is not met as evidenced by: (A) Based on observation, review of documentation, and staff interviews, the pharmacy failed to provide training for safe handling of hazardous medications. Staff #S405 was observed handling chemotherapy medications in a manner that did not promote patient safety, worker safety, or environmental protection.  (B) Based on observation, interview, and policy review, hospital #2 failed ensure that pharmaceutical services were provided in accordance with accepted standards bags of IV fluids were stored next to a partially filled bottle of drinking water in a supply warehouse where temperature and humidity were not monitored. In addition, a medication Pyxis machine had dried drippage with debris and cleaning of the Pyxis	A 492		

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A 492	<p>Continued From page 222 was not addressed in pharmacy policy.</p> <p>Findings:</p> <p>During a tour of the pharmacy warehouse at hospital #2 on the morning of 9/23/19 accompanied by staff #S404, staff #S405 was observed unpacking a box of chemotherapy drugs. Staff #S405 was not wearing gloves or any protective equipment. The chemotherapy medications were place in a gray plastic bin, the plastic bin was place on a metal shelf; there were medical supplies observed on the shelves below. After unpacking other pharmacy supplies, staff #S405 placed the gray plastic bin on a metal cart. The plastic bin containing the chemotherapy medications was uncovered. Staff #S405 rolled the cart from the pharmacy warehouse to central pharmacy located a significant distance from the warehouse, exposing the chemotherapy medications to the public environment. A chemotherapy spill kit was not available for possible spillage. The cart was rolled into the negative pressure room where medications were stored in central pharmacy. Staff #S405 placed the chemotherapy medications in the refrigerator in the negative pressure room.</p> <p>An interview was conducted with staff #S405 on 9/23/19 at 12:57 PM, in the pharmacy warehouse. The surveyor asked staff #405 if he had training for handling chemotherapy medications. Staff #S405 said no.</p> <p>Review of policy 594.0, last review date 11/13/2018, stated, "All hazardous drugs shall be</p>	A 492			

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A 492	<p>Continued From page 223</p> <p>handled by competent trained personnel in a manner that reduces risks to human health, the environment, and/or property. D. Closed system drug-transfer device (CSTD): A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system. II. Departments with employees who handle GD, on a regular basis must: Document employee competency to handle HD. 6. Ensure that appropriate personal protective equipment is available and worn by employees. A. HD's shall be handled under conditions that promote patient safety, worker safety and environmental protection."</p> <p>In an interview on 9/23/19 with staff #S404 the findings were confirmed.</p> <p>During a tour of the clean supply warehouse at hospital #2 on 09/19/19 beginning at 11:10 a.m., accompanied by Staff #S222, Staff #S225, and Staff #S228, observations revealed the following in part:</p> <p>A partially filled bottle of drinking water lying horizontal next to 1000 cc bags of 5% Dextrose in 0.45% Saline IV fluids - on the bottom of a cart with a cardboard box lying on top of one bag of the IV fluids and a plastic bin lying on top of 500 cc bag of 0.9% Sodium Chloride IV fluids.</p> <p>The above findings were confirmed with Staff #S228 in an interview on 09/19/19 at 11:32 a.m., in the clean supply warehouse at hospital #2.</p>	A 492		



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A 492	<p>Continued From page 224</p> <p>During an interview of Staff #S77 and Staff #S230 on 09/19/19 at 11:50 a.m., in the clean supply warehouse at hospital #2, both confirmed that neither temperature or humidity were being monitored in the warehouse at the time of the survey.</p> <p>During an inspection of the Pyxis cabinet for the storage of medications in the sterile corridor of the operating suite at hospital #2 on 09/23/19 at 11:28 a.m. in the presence of Staff #S205, observation revealed dried drippage on the inside and outside of the clear plexi-glass door of the bottom shelf and areas of black debris to the lower shelf that could be removed from both areas by wiping them with an Oxivir wipe.</p> <p>In an interview on 09/23/19 at 11:28 a.m., in front of the Pyxis cabinet in the sterile corridor of the operating suite at hospital #2, Staff #S205 confirmed the above findings.</p> <p>The hospital policy no. 550.00 entitled "Automated Dispensing Cabinets," with an effective date of "4/08," and a last review date of "08/27/2019," was reviewed on 09/24/19 at 1:58 p.m., in a conference room at hospital #2 and stated the following in part, "POLICY STATEMENT: The Automated Dispensing Cabinets (ADC) shall be used to increase patient safety, expedite medication administration, and ensure proper documentation of medication actions." The policy did not address the cleaning of the Pyxis.</p>	A 492			

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A 492	<p>Continued From page 225</p> <p>In an interview on 09/24/19 at 1:59 p.m., in a conference room at hospital #2, Staff #S495 confirmed that the policy did not address cleaning of the Pyxis and that hospital does not have a policy on cleaning of the Pyxis.</p> <p>In an interview on 09/24/19 at 9:33 a.m., in an administrative office at hospital #2, Staff #498 confirmed that the hospital has nothing in a policy that addresses cleaning of the Pyxis machine for medication but stated, "Techs are encouraged on a daily basis to clean the Pyxis when they are delivering meds," "It's an expectation," and "Staff do monthly audits to check for expired meds. That is an opportunity to clean the Pyxis."</p> <p>On 9/19/19 at 11:10 am, a tour of the clean supply warehouse at hospital #2 was performed. The observations noted during this tour are as follow:</p> <p>A. Several opened supply blue crates were seen opened with the contents exposed. Several of these crates had IV fluids such as Normal Saline, Lactated ringers and 0.45% saline in various volumes.</p> <p>B. Several IV fluid bags and opened crates with IV fluids were noted to be stored with items such as wheel chairs, metal pallets, and trash.</p> <p>C. Oral Contrast solution drinks left in an opened box exposed to environment.</p> <p>These observations were made in the presence and confirmed by staff #S222. The warehouse was described as a clean environment by staff #S222.</p>	A 492			

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A 494	<p>PHARMACY DRUG RECORDS CFR(s): 482.25(a)(3)</p> <p>Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.</p> <p>This STANDARD is not met as evidenced by: Based on review of documentation and interviews with facility staff, the facility failed to develop accountability procedures to ensure controlled medications that were dispensed as a continuous intravenous (IV) infusion were not diverted by unauthorized persons. This unsafe condition placed patients at risk of not receiving the actual amount of prescribed medications and potentially being cared for by an impaired staff member in 4 of 4 random observations Patient #s 163, 164, 239, and 705</p> <p>Findings:</p> <p>During the tour of 4E Intensive Care Unit (ICU) in Hospital #1 on the morning of 9/23/19 with Staff #S400 it was observed:</p> <p>Patient #163 was receiving a continuous IV infusion of Fentanyl, a narcotic drug, through a standard infusion pump that could be used for all types of medications. The tubing used to connect the bag to the infusion pump and connect the infusion pump to the patient's IV site was observed to be standard IV tubing. This tubing was observed to have multiple luer-lock ports where a syringe could be used to withdraw or add medications between the medication bag and the pump. This unsecured set-up has the likelihood for unauthorized persons to access and withdraw narcotics without detection.</p>	A 494			

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A 494	<p>Continued From page 227</p> <p>Patient #164 was receiving a continuous IV infusion of Fentanyl, a narcotic drug, through a standard infusion pump that could be used for all types of medications. The tubing used to connect the bag to the infusion pump and connect the infusion pump to the patient's IV site was observed to be standard IV tubing. This tubing was observed to have multiple luer-lock ports where a syringe could be used to withdraw or add medications between the medication bag and the pump. This unsecured set-up has the likelihood for unauthorized persons to access and withdraw narcotics without detection.</p> <p>In an interview, Staff #S425 was asked, "What would prevent anyone from drawing Fentanyl out of the proximal port closest to the Fentanyl IV bag and replacing it with something like saline?" Staff #S425 replied, "I guess nothing." The surveyor further asked, "Do you have any IV tubing that goes with this Alaris pump that has no extra luer-lock ports?" Staff #S425 replied, "Yes, we have the low sorbing tubing set that has no extra ports." Staff #S425 provided the surveyor a brand new IV tubing set without additional ports, the package was labeled, "BD Alaris Pump Infusion Set Low Sorbing Tubing."</p> <p>In an interview on the afternoon of 9/23/19, Staff #S129 acknowledged the findings above.</p> <p>On 9-26-2019 at 10:57 AM, a tour was made of the Medical Intensive Care Unit at Hospital #2. Staff #94 reported that two Fentanyl continuous infusions were currently being used. One was in ICU room 11 and the other was in ICU room 16.</p>	A 494			

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A 494	Continued From page 228 Both infusions were observed to be through a standard infusion pump that could be used for all types of medications. The tubing used to connect the bag to the infusion pump and connect the infusion pump to the patient's IV site was observed to be standard IV tubing. This tubing was observed to have multiple ports where a syringe could be used to withdraw or add medications between the medication bag and the pump. This unsecured set-up has the likelihood for unauthorized persons to access and withdraw narcotics without detection.	A 494			
A 503	Staff #S705 was caring for Patient #239 in ICU room 16. Staff #S705 was interviewed and asked what would prevent someone from removing the narcotic from the access port on the tubing and replacing it with a compatible fluid like normal saline. Staff #S705 replied, "Nothing". <b>CONTROLLED DRUGS KEPT LOCKED</b> CFR(s): 482.25(b)(2)(ii)  Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.  This STANDARD is not met as evidenced by: Based on observation, review of documentation, and staff interviews, the facility failed to store controlled substances in a secure manner. Controlled substances were observed unsecured on a pallet in the pharmacy warehouse in 1 of 2 hospital pharmacies toured. Hospital #2  Findings:	A 503			

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A 503	Continued From page 229  During a tour of the pharmacy warehouse at hospital #2, on the 9/23/19 at 11:20 am, accompanied by staff #S404, 4 boxes of controlled substances (CS) were observed on a pallet. Staff #S404 said, the CS are delivered with the medications and supplies. The CS medications remain on the pallet in the warehouse until the pharmacy technician delivers it to central pharmacy.  Review of sign in and out form reveal the vendor delivered the CS at 9:02 am. Staff #S408 was observed loading the CS into a metal cart with combination lock at 11:35 am.  Review of Management and Accountability of controlled substances policy no. 582.00, last review date 09/23/2019, stated, " III. Storage and Security. A. Only authorized personnel shall have access to CS. C. Security of CS in areas that do not have ADC. 1. CS in non-ADC areas will be stored and secured in a locked cabinet or secured medication room.	A 503			
A 505	UNUSABLE DRUGS NOT USED CFR(s): 482.25(b)(3)  §482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use This STANDARD is not met as evidenced by: Based on observation, review of documentation, and interview, it was determined that the hospital failed to ensure that expired medications were removed from stock. Expired medications were	A 505			

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A 505	<p>Continued From page 230</p> <p>not removed from pharmacy stock and available to be dispensed in 2 of 28 centers pharmacy monitored.</p> <p>Findings:</p> <p>During a tour of out patient clinic (#3) on the late morning of 9/25/2019, observation in the pharmacy revealed that stored among other medications on a shelf was one 200 ml bottle of Acyclovair 200 mg/5 ml oral suspension. The labeling on the bottle listed the "written date" as 7/25/2018. The "filled date" as 7/30/2018, and the "Expires beyond use date" as 7/30/2019.</p> <p>Review of pharmacy policy entitled "Expired/Beyond Use Date Medication Preparation Removal," stated, "In an effort to ensure patient safety and meet regulatory requirements regarding outdated product removal, the Department of Pharmacy (DOP) has outlined a procedure for flagging and removing expired/beyond use medications to prevent them from being dispensed to Harris Health System patients." Page two stated under the procedure section, "A. All medication areas shall be inspected routinely for cleanliness, expiration dates, and beyond use dates." "D. The medication areas shall be inspected, and documentation completed by the 25th of each month." "E. Expired/beyond use medications shall be removed from stock and placed in the designated expired medication section (quarantined from medication areas) within the pharmacies."</p>	A 505			

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A 505	Continued From page 231  In an interview with staff member #S527 the above finding was confirmed.  Observation on 9/16/19 at 2:00 PM, of Hospital 2's Teen Clinic located on the first floor revealed the following: in the pharmacy clinic, located inside and used exclusively for the Teen Clinic, were five full bottles of the antibiotic Amoxicillin (with 60 capsules in each) that expired on 8/19.  In an interview on 9/16/19 at 2:00 PM, with Family Nurse Practitioner Staff #S379, she stated that the expired medications should have been discarded and not available for patient use. She then promptly discarded all five bottles of the Amoxicillin.	A 505			
A 619	ORGANIZATION CFR(s): 482.28(a)  Organization  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to provide an organized, clean, and sanitary dietary department for Hospital 1, in 1 of 2 hospital dietary departments toured.  Findings:  Observations during a tour of Hospital 1's kitchen on 9/16/19 and 9/17/19, accompanied by Staff #S50 and Staff #S52 revealed the following:	A 619			



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A 619	<p>Continued From page 232</p> <ul style="list-style-type: none"> <li>- Staffs #s S50, S165, and S164, in the food production areas with exposed beards and moustaches.</li> <li>- A large food storage bin with a plastic scoop's handle sitting on the dry beans.</li> <li>- (2) chef's knives with dried food debris stored in the knife holder readily available for use.</li> <li>- The large meat slicer with dried food debris around the cutting blade readily available for use.</li> <li>- The manual tomato slicer had dried food debris on the cutting blades available for use.</li> <li>- (2) Cutting boards with a dark substance left in the deep cuts on the boards.</li> <li>- A dark brown and yellow slime growth in the mop drain, located in the dish room.</li> <li>- (2) mops being stored in dirty water.</li> <li>- (2) full containers of individual patient's butter, to be used for the patient's lunch tray assembly, sitting out on a counter at room temperature. The butter's packaging reflected the item required refrigeration.</li> </ul> <p>Further observation on 9/17/19 revealed, a reach-in refrigerator with a digital external temperature of 44 degrees Fahrenheit. The reach-in refrigerator did not have an internal thermometer.</p> <p>During interviews on the morning of 9/16/19 and</p>	A 619			

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A 619	<p>Continued From page 233</p> <p>9/17/19, Staff #S166 confirmed the findings. Staff #S166 stated the digital thermometer's temperature probe is placed in the middle of the refrigerators. Staff #S166 was unable to provide a policy or procedure for the checking of the internal product temperatures for the products at the warmest part of the refrigerators, by the door.</p> <p>Review of the facility policy #6.10 Food and Nutrition Services Dress Code (dated 10/16/2018) reflected, "A. All hair shall be covered at all times while working in the production area and cafeteria, F. Facial hair must be well groomed and trimmed or it must be covered with a beard restraint to protect exposed food, clean equipment, utensils and linens."</p> <p>Review of the TFER (Texas Food Establishment Rules) October 2015 reflected the following:</p> <p>228.186(f) Drying mops (f) Drying mops. After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.</p> <p>228.111(b) Cutting surfaces. (b) Cutting surfaces. Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized or discarded if they are not capable of being resurfaced.</p> <p>228.114(a)(5)(A) Surfaces of utensils and equipment contacting food that is not time/temperature control for safety shall be cleaned at any time when</p>	A 619			

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A 619	<p>Continued From page 234 contamination may have occurred.</p> <p>228.68(b)(1) In-use utensils, between-use storage. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored except as specified under subsection (a) of this section, in the food with their handles above the top of the food and the container.</p> <p>228.43(a)Hair Restraints (a) Except as provided in subsection (b) of this section, food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens, and unwrapped single-service and single-use articles.</p> <p>228.106(k)(1) Food thermometers provided and accessible Temperature measuring devices. (1) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.</p> <p>(2) Except as specified in paragraph (3) of this subsection, cold or hot holding equipment used for time/temperature controlled for safety (TCS) food shall be designed to include and shall be equipped with at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.</p>	A 619			

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A 701	<p><b>MAINTENANCE OF PHYSICAL PLANT</b> CFR(s): 482.41(a)</p> <p>The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of documentation, and interview, it was determined that Hospital 1, Hospital 2, and Clinic 3 administrative staff failed to ensure that the physical environment was maintained to protect the safety and well being of the patients:</p> <p>*Hospital 1: automatic external defibrillator (AED) not working, patient bathroom emergency call light pulls absent or wrapped around grab bars ( 8 +), numerous wall-mounted fluorescent lights not working, leaking pipe in basement with exposed electrical wire nearby, eye wash station absent in area where chemicals stored, and dust on ice machines and other areas.</p> <p>*Hospital 2: improper storage of potentially hazardous dialysis solution, stained ceiling tiles noted in multiple departments, torn vinyl on numerous chairs in patient /family waiting areas. Dialysis solution stored in environment not temperature controlled.</p> <p>Clinic 3 : leaking chemicals in chemical storage cabinet, numerous wall-mounted fluorescent lights not working, dirty floor drain.</p> <p>Findings:  Hospital 1:</p>	A 701			

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A 701	<p>Continued From page 236</p> <p>Tour of the hospital 1 basement on the morning of 9/16/2019:</p> <p>In corridor 81 of the basement, there were five overhead ceiling mounted fluorescent light fixtures containing what appeared to be dead insects. In an interview with staff member #S112 at time of observation, the finding was confirmed.</p> <p>Visible light was observed under the exterior door to the loading dock, this provided the potential for a point of entry for insects and rodents. In an interview with staff member #S126 at time of observation, the finding was confirmed.</p> <p>Room B-MM81 003ab, dirty equipment (2 each IV poles) was found stored with clean and covered equipment (bedside commodes). Additionally, it was observed that there was visible dust on the paper towel dispenser in the room. In an interview with staff member #S116 at time of interview, the findings were confirmed.</p> <p>Tour of the Emergency Department on the afternoon of 9/16/2019:</p> <p>In the "sort room," one of three ceiling mounted fluorescent light fixtures was not working.</p> <p>In the Emergency Department waiting room, there was a 3-person bench which was found to have multiple cracks in vinyl covering on the seating area on two of the seats.</p> <p>In the janitor closet located in room 1 -EC 60 003, the ceiling mounted fluorescent light fixture was dirty in appearance.</p>	A 701			

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A 701	<p>Continued From page 237</p> <p>In room 1 ED 70 001 the EM Research Lab, one of the ceiling mounted fluorescent light fixture was not working.</p> <p>In the bulk storage room, 2 of 4 ceiling mounted fluorescent light fixtures were not working.</p> <p>In storage room F10, one of the ceiling mounted fluorescent light fixtures was not working.</p> <p>In the Pediatric triage room 1 PE 51 008, the ceiling light fixture had what appeared to be dead cockroach in it.</p> <p>In room 1 FC 43-003 the core supply room, the top of the DCP 1-10 panel had visible dust on it.</p> <p>The ice machine located in Core D had visible dust on top of the ice machine.</p> <p>In an interview on the afternoon of 9/16/19 during the time of observations with staff member #S118, the findings from the emergency department were confirmed.</p> <p>Tour of the hospital on 9/17/2019:</p> <p>Hospital 1:</p> <p>Observation in the Central Sterile processing hallway at approximately 10:55 a.m. The AED (automatic external defibrillator) located in the central sterile processing hallway (located adjacent to the men's locker room 2937) did not work.</p> <p>During a tour of the central sterile processing area on the morning of 9/17/2019, the surveyor</p>	A 701		

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A 701	<p>Continued From page 238</p> <p>asked staff member #S58 if the AED worked. Staff member #S58 attempted to determine if the AED was operable but was unable to make the AED function. In an interview with staff members #S58, #S132, and #S133 it was confirmed that the AED did not function.</p> <p>Nursing unit 5C tub room, the emergency pull cord was observed wrapped on one of the stainless-steel grab bars. This was confirmed in interview with staff member #S132.</p> <p>Biohazard room on 5C had one of the ceiling mounted fluorescent light tubes not working. This was confirmed in interview with staff member #S134.</p> <p>Linen room on 5C had one of the ceiling mounted fluorescent light tubes not working. This was confirmed in interview with staff member #S132.</p> <p>Tour of the hospital on 9/18/2019:</p> <p>Hospital 1:</p> <p>Nursing Units</p> <p>Soiled Utility room #61C81014, was observed to contain a black plastic linen cart, inside the cart was a sign which stated, "No trash (any) in linen cart inside the 6E Soiled Utility Room (such gowns, gloves, paper towels)." Observation inside the cart revealed approximately 6 blue disposable examination gloves in the bottom of the cart. This was confirmed in an interview with staff members #S314.</p> <p>Ice machine in patient nourishment room</p>	A 701			

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A 701	<p>Continued From page 239</p> <p>61C82-001, visible dust was observed on top of the ice machine. This was confirmed in interview with staff member#S321.</p> <p>On the fourth floor GYN unit in the tower building, patient restroom 424, was observed to have the emergency pull cord wrapped around the stainless-steel grab/assist handle. On the fourth floor OB unit in the tower building, patient restroom 486 was observed to have the emergency pull cord wrapped about around the stainless-steel grab/assist handle. This was confirmed in interview with staff member #S132.</p> <p>Tour of the hospital's water softener storage area on the afternoon of 9/24/2019:</p> <p>Hospital 1:</p> <p>Water hardness testing reagents were expired. During a tour of the "salt room" on the afternoon of 9/24/2019, it was observed in a wall mounted cabinet that there were 6, 60 ml bottles of Hardness #7 testing reagent. The expiration dates on these bottles were 6/2015, 8/2016, 11/2016 (missing screw on top), 8/2019 x 2, and 2/2019. Also found was a container of Oxivir Tb wipes which had an expiration date of 12/2018.</p> <p>The interior of the cabinet in which the above was stored was dirty in appearance and there was a 500 ml Nalgene bottle which was approximately 2/3 full labeled "Feed Water" no date was found on this container as to when it was prepared.</p> <p>Observation of the brine tank revealed that it was partially uncovered exposing the interior content of the tank to the atmosphere.</p>	A 701			



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A 701	<p>Continued From page 240</p> <p>When the surveyor looked in the tank there were small pieces of visible debris observed floating on the water in the tank. There was also a valve above the brine tank which was dripping into the tank.</p> <p>Interview with staff member #S316 and staff #S525 at the time of observations the above findings were confirmed.</p> <p>In a follow-up interview on the morning of 9/25/2019 with staff member #S113, the survey team was informed that the brine tank should be covered.</p> <p>Tour of hospital outpatient location (Clinic #3) on the morning of 9/25/2019:</p> <p>Clinic 3:</p> <p>Clean Storage room in the Laboratory, contained ceiling mounted fluorescent light fixture which had two light tubes that were not working.</p> <p>Exterior doors from the electrical room and mechanical room had visible light observed at the threshold. This provided the potential for a point of entry for insects and rodents.</p> <p>Electrical room had eight ceiling mounted fluorescent light fixture tubes which were not working.</p> <p>The floor drain in the sterile instrument room was dirty in appearance with visible debris in the drain.</p> <p>An examination on the yellow flammable chemicals cabinet located in the mechanical</p>	A 701		

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A 701	<p>Continued From page 241</p> <p>room revealed that the upper shelf was wet in appearance as if one of the containers was leaking and lower shelf was also wet in appearance. The above findings for outpatient clinic #3 were confirmed during the observations in an interview with staff member #S526.</p> <p>Storage closet in the central supply room had one ceiling mounted fluorescent light tube not working. This was confirmed during the observation in an interview with staff member #S528.</p> <p>Review of hospital policy number 7507.01 entitled "Maintenance of Equipment" stated, "This policy assigns responsibility, establishes requirements, and provide procedures for the efficient and timely user and support maintenance of facilities, medical, and dental equipment at ---- Health System activities."</p> <p>Review of hospital policy number 7200 entitled, "Environmental Services Cleaning Guidelines" stated in the Purpose section: "To reduce the risk of hospital acquired infections from transmission between patients, personnel, in an overall healthcare environment; To ensure standardized cleaning protocols that enhance our patient experience by providing a high level service to produces a clean, safe and healthy environment; and To foster collaboration between the hospital's Infection Prevention Program and Environmental Services."</p> <p>Hospital #1:</p> <p>1. Leaking water pipes were observed at the</p>	A 701			

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A 701	<p>Continued From page 242</p> <p>facility Mechanical area on the basement floor. Next to one of the leaking pipe was uncovered junction box with visible exposed wires.</p> <p>2. Some patient bathrooms had no emergency pull cord alarms installed.</p> <p>3. Emergency eye wash at the mechanical area on the basement floor where facility stored hazardous/corrosive chemicals had been removed.</p> <p>4. The stairwells at the facility car garage appeared grossly filthy and had visible debris, dirt, brown stains, and offensive odor.</p> <p>During the tour of hospital (#1) mechanical area on the basement floor on 09/16/19 at 10:15 a.m., two leaking water pipes was observed dripping water to the floor. Next to one of the leaking pipe was uncovered junction box with visible wires in it. These findings were confirmed by staff member #S112.</p> <p>Further observation revealed an emergency eye wash had been removed from the mechanical area of the basement floor. Hazardous and corrosive chemicals labeled CL2840 and unlabeled 5 gal black gas cylinder were stored in the basement. Interview with staff member #S112 revealed, there was no emergency shower or eye wash available. He said it had been removed since "thought we didn't need it."</p> <p>Observation of the hospital #1 Emergency Center on 09/16/19 at 12:10 p.m., revealed, patient</p>	A 701			

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A 701	<p>Continued From page 243</p> <p>bathroom 1-EC 70 005 had no emergency pull cord installed. This was confirmed by staff member # S 370.</p> <p>Observation on hospital #1 level 3 C- High Risk antepartum on 09/17/19 at 10:12 a.m., revealed, patients bathroom 3-C 51 027 had no emergency pull cord installed. This was confirmed by staff member # S 383.</p> <p>Observation on hospital #1 level 6 F- GI Lab on 09/18/19 at 10:25 a.m., revealed, patients bathroom 6-GI 70 005 had no emergency pull cord installed. This was confirmed by staff member #S57.</p> <p>Interview with staff member #S57 at the time of observations revealed that patients on GI and critical care patients used the 6-GI 70 005 restroom.</p> <p>Policy on emergency pull cords requested, the hospital had no policy in place.</p> <p>Observation of the hospital #1 garage stairwells on 09/24/19 revealed ,they were grossly filthy with visible debris, dirt, brown stains and offensive odor. This was confirmed by staff member #S113 who reported they were "in the process of cleaning them."</p> <p>Review of facility policy # 7507.01 titled "Maintenance of Equipment" with last review date of 08/30/2019, reflected the following purpose, "</p>	A 701			

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A 701	<p>Continued From page 244</p> <p>...provide procedures for the efficient and timely user and support maintenance services of facilities."</p> <p>Review of facility policy # 7200 titled "Environmental Services cleaning guidelines" with a last reviewed date 09/11/2019, reflected the following purpose, "To ensure standardized cleaning protocols that enhance our patient experience by providing a high-level service to produce a clean, safe and healthy environment." Hospital 2:</p> <p>Unsafe storage of dialysis solution:</p> <p>Observation of the Hospital #2 warehouse on 9/25/2019 at 10:10 AM showed six (6) one-gallon containers of Minncare Cold Sterilant used in dialysis, not in their original shipping boxes. Batteries and oxygen tanks were stored in the same area as the solutions.</p> <p>In an interview with Staff #S227 (Materials Management Supervisor) in the Hospital #2 warehouse on 9/25/2019 at 10:10 AM, he stated that the containers of Minncare Cold Sterilant and Renal Pure should have been in boxes. He stated, he did not know the hazards identification of the two solutions. He concluded by saying the warehouse gets very hot during the summer, the temperature is not monitored, and the solutions should not be stored in a hot warehouse.</p> <p>In an interview with Staff #S470 (Manager of Safety and Environmental Health) at Hospital #2 on 9/25/2019 at 10:20 AM, he stated he did not</p>	A 701			

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A 701	<p>Continued From page 245</p> <p>know the hazards identification of the two solutions. He concluded by saying, the warehouse gets very hot during the summer.</p> <p>Record review of Safety Data Sheet for Minncare Cold Sterilant (product code: 3029765, 3029764, 3029817), revised 2/19/2015, showed: " ... Oxidizing liquid ... May cause fire or explosion ... Causes severe skin burns and eye damage. Harmful if inhaled. May cause respiratory irritation ... Keep ... in a cool, well-ventilated place. Store away from other materials ... Store at temperatures not exceeding 75 degrees Fahrenheit ... Store locked up."</p> <p>Hospital 2:</p> <p>Observation on the morning of 9/16/19 at Hospital 2 revealed there were four heavily stained ceiling tiles in facility's main Service Hallway. In an interview with Facility's Director Staff #S229 at time of findings, he stated, the stained ceiling tiles should not have been there.</p> <p>Observation on the morning of 9/17/19 of Hospital 2's Emergency Center's Patient Waiting Room showed there were three heavily stained ceiling tiles. In an interview with Facility's Director Staff #S229 at that time, he stated, the stained ceiling tiles should not have been present.</p> <p>Observation on the morning of 9/16/19 of Hospital 2's Outpatient pharmacy waiting room showed, there were three chairs that had their vinyl armrests torn, exposing the foam padding from underneath.</p>	A 701			

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A 701	Continued From page 246  Observation on the morning of 9/17/19 of Hospital 2's NICU (neonatal intensive care unit) waiting room showed, there were two chairs with torn vinyl armrests, exposing the foam padding underneath.  Observation on the morning of 9/18/19 of Hospital 2's Radiology waiting room showed, there were eight chairs with torn vinyl armrests, exposing the foam padding underneath.  Observation on the morning of 9/19/19 of Hospital 2's third floor ICU waiting room showed, there were two chairs with torn vinyl armrests, exposing the foam padding underneath.  Observation on the afternoon of 9/19/19 of Hospital 2's Day Surgery waiting room showed, there were three chairs with torn vinyl armrests, exposing the foam padding underneath.	A 701			
A 724	FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE CFR(s): 482.41(d)(2)  Facilities, supplies, and equipment must be maintained to ensure an acceptable level of	A 724			

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A 724	<p>Continued From page 247</p> <p>safety and quality. This STANDARD is not met as evidenced by: Based on observation, review of documentation, and interviews with facility staff, the facility failed to properly maintain patient care equipment and supplies in Hospitals 1 and 2, and Clinic # 6.</p> <p>Hospital 1 :</p> <p>A. Biomedical inspections were not completed for patient care equipment in radiology and emergency departments.</p> <p>B. X-ray machine in radiology and equipment in rehabilitation was not maintained in a sanitary manner.</p> <p>C. Patient equipment was not stored appropriately.</p> <p>D. Trash and dirty linen were not disposed of in a sanitary &amp; safe manner.</p> <p>E. Housekeeping cart was left unattended and unlocked providing public access to hazardous cleaning chemicals.</p> <p>Hospital 2:</p> <p>F. Emergency crash carts were not maintained and inspected in a manner that ensured the safety and quality of supplies and equipment in the carts.</p> <p>G. Environmental issues were observed to include : unsafe storage of equipment and supplies; unsanitary conditions related to a</p>	A 724			



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A 724	<p>Continued From page 248</p> <p>cracked countertop and Pyxis medication storage; and improper disposal of trash.</p> <p>Clinic 8 : glucometer lacked a biomedical inspection per policy.</p> <p>Findings:</p> <p>Hospital 1:</p> <p>A. Biomedical equipment inspection:</p> <p>Radiology:</p> <p>During a tour of hospital #1 interventional radiology department 9/17/19 at approximately 9:00 am, two Vortex Genie 2 shakers used to mix Onyx liquid embolic material (liquid embolic agent for the treatment of intracranial aneurysms) were observed in the Biplane-Neuro Room that had no biomedical inspection tags of any kind affixed. In an interview during the tour at approximately 9:00 am, staff #111 acknowledged there was no evidence of biomedical inspection of the Vortex Genie shakers.</p> <p>The facility policy titled "Maintenance of Equipment" #7507.01, review date 8/19, reflected in part, "C. The Pavilion Director(s), Facility and Biomedical Engineering Services will ...3. Implement a maintenance program for the repair, preventative maintenance, safety testing and CVC (Calibration/Verification/Certification) of equipment located at ____ Health Facilities."</p> <p>Hospital 1:</p> <p>A. Biomedical equipment inspection :</p>	A 724			

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A 724	<p>Continued From page 249</p> <p>Emergency Center [and at the offsite Clinic #6] :</p> <p>During the tour of the hospital #1 Emergency center on 09/16/19 at 12:15 p.m., one glucometer machine was noted not to have a preventive Maintenance (PM) sticker on it. This was confirmed by staff member #S370. She reported that, "I didn't know it had no PM sticker. It's supposed to have one."</p> <p>Tour of Offsite clinic #6 on 0909/23/19 at 09:23 a.m., revealed, a glucometer machine with no inspection sticker in it. This was confirmed by staff member # S316.</p> <p>B. X-ray machine in radiology and equipment in rehabilitation not maintained in a sanitary manner:</p> <p>During a tour of the hospital #1 Radiology department on 09/16/19, in the company of staff member #S120, revealed a digital portable X ray machine was dusty and had white stains on it. This was confirmed by staff member# S120.</p> <p>During a tour of the hospital #1 Rehab service area on 09/17/19 at 09:56 a.m., in the company of staff member #S121, revealed, the Tilt table and cad chair was observed to be dusty. The Tilt table and cad chair on Hospital #1 level 2- rehab services department were observed to be dusty. Dirty towels were observed thrown in a trash can. Used tweezers and spoons were observed disposed in dirty linen bin.</p> <p>C. Patient equipment was not stored appropriately:</p>	A 724			

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A 724	<p>Continued From page 250</p> <p>During a tour of the hospital#1 Rehab service area on 09/17/19 at 09:56 a.m., in the company of staff member #S121, revealed, patient commodes and shower chairs were observed inappropriately stored and crammed in a bathroom used by staff members.</p> <p>D. Trash and dirty linen were not disposed of in a sanitary and safe manner:</p> <p>Continued observation in hospital 1 rehab area on 09/17/19, showed dirty wash towels thrown in a trash can. Used tweezers and spoons were observed disposed in a dirty linen bin. Patient commodes and shower chairs were observed crammed in a bathroom used by staff members. These findings were confirmed by staff member # S121.</p> <p>A tour of the hospital #13 B - Texas Health Steps on 09/17/19 at 10:15 a.m., revealed, a draining sink at the janitor's room 3NO 32 023 appeared grossly dirty and had visible brown stains. The floor had visible brown stains. Staff member #S123 confirmed these findings. She reported "I rarely come here. It's supposed to be cleaned after use."</p> <p>Review of facility policy # 7507.01 titled "Maintenance of Equipment," with last review date of 08/30/2019, reflected the following purpose, " ...provide procedures for the efficient and timely user and support maintenance services of facilities, medical and dental equipment." It stated, "the Director of each clinical activity or department will implement an</p>	A 724			

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FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>450289</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>09/27/2019</b>
NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 724	<p>Continued From page 251</p> <p>equipment operator PM program that ensures equipment operator monitoring and maintenance before, during, and after use of each piece of equipment."</p> <p>Review of facility policy # 7200 titled "Environmental Services cleaning guidelines," with a last reviewed date 09/11/2019, reflected the following purpose: "To ensure standardized cleaning protocols that enhance our patient experience by providing a high-level service to produce a clean, safe and healthy environment." Hospital 1:</p> <p>E. Housekeeping cart was left unattended and unlocked providing public access to hazardous cleaning chemicals.</p> <p>Findings:</p> <p>On 9/20/2019 at 1:40 PM, during a tour of the Medical Surgical Unit hall, it was noted that a housekeeping cleaning cart was open to public view and the environmental/housekeeping staff was not present. There were several bottles of Oxivir disinfectant in the housekeeping cart.</p> <p>On 9/20/2019 at 2:00 PM, an environmental/housekeeper was interviewed. The environmental worker #S724 stated that she can stay away from her cleaning cart for long periods of time. When asked if the cart had a locked compartment where she can keep the disinfectant safe from the public, the worker stated, "No, the managers are trying to put locks on these carts but the one I am using today has no lock. I could have closed the drawers".</p>	A 724			

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A 724	<p>Continued From page 252</p> <p>On 9/20/2019 at 2:15 PM, a tour of Medical Surgical Unit 5E was conducted. It was noted that the housekeeping cart was unattended, open and in full public view. In the cart were Oxivir bottles and large Ecolab soap containers. It was noted that an environmental/housekeeper was inside a patient's room. Three minutes later the housekeeper came back to the cart.</p> <p>On 9/20/2019 at 2:03 PM, environmental/housekeeper #S725 came out of a patient's room. When asked if the cleaning cart had a lock she stated, "No". The worker stated that she forgot to close the cart drawers.</p> <p>Record review of the Competency Check List for environmental/housekeeper #S724. The Last competency check list was signed and dated on 3/28/2017. Under "Can you leave your cart unattended" the reply was "Never". According to this document the employee failed this competency. The employee failed because according to management the answer was "For 30 minutes".</p> <p>Record review of the Competency Check List for environmental/housekeeper #S725. The last competency check list was signed on 4/19/2017. Under "Can you leave your cart unattended" the reply was "Never". According to the document, the employee failed this competency. The employee failed because according to management the answer was "For 30 minutes".</p> <p>Record review for both employees Competency Assessment EVS (Environmental Service</p>	A 724			

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A 724	<p>Continued From page 253</p> <p>Technician 1) showed that both employees were retrained on 9/22/2019, two days after this finding.</p> <p>On 9/26/2019 at 8:30 am, Staff #S726 and #S727 and were interviewed. During the interview, the Staff stated that they try to have the Competency Check List completed for every environmental service staff member every year. They indicated that all the employees had to complete the hospital training requirements annually. However, it did not cover the duties and responsibilities of the environmental service staff. Staff #S726 stated that they follow the Life Safety Code standards in which the housekeeping cart can be left unattended and in public view for 30 minutes. When it was mentioned that this is a health survey and not a Life Safety Code survey, the Staff stated that it is the hospital policy that the environmental staff can leave the cleaning carts unattended and in public view for 30 minutes.</p> <p>On 9/26/2019 at 9:00 am, Staff #726 came back to the interview room and stated, he was wrong, that there is no hospital policy allowing the environmental/housekeeper staff to leave the cart open and unattended for 30 minutes. His expectation is that all the cleaning carts and cleaning supplies be locked away for safety reasons. The Staff stated that they were in the process of installing locks on those cleaning carts.</p> <p>Hospital 2:</p> <p>F. Emergency crash carts were not maintained and inspected in a manner that ensured the safety and quality of supplies and equipment in</p>	A 724			

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A 724	<p>Continued From page 254 the carts.</p> <p>Findings:</p> <p>During a tour of Unit 3A at Hospital #2 on 9-16-2019, an emergency Crash Cart was opened and inspected. The cart drawers were observed to be locked with plastic locking tags of various colors that were numbered. When a drawer was opened, the lock tag had to be broken off. The purpose of the tags was to alert staff if the drawer had been opened or tampered with, ensuring that the necessary supplies were available in an emergency.</p> <p>Crash Carts were required to be checked daily and documented on a review log. Review of the log for the Crash Cart showed that the staff were to inspect that the lock was intact. However, there was not a spot to record the number on the lock tag.</p> <p>A search of internet sites showed that the lock tags being used, Health Care Logistics Heavy Duty are sequentially numbered lock tags. Since the serial numbers were not logged and verified at each check, it was possible for unauthorized persons to open the cart, remove equipment and supplies including emergency medications stored in the cart, and reseal the drawer with another locking tag. This could result in emergency supplies and equipment being unavailable to an emergency response team.</p> <p>Once open, the sterile equipment inside drawers was found to be stored in a manner that compromised sterility of the packaging. Packages of sterile instruments and supplies were bundled together with rubber bands that had been tightly</p>	A 724			

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A 724	<p>Continued From page 255</p> <p>placed, tearing and puncturing the sterile wrapping. Nonsterile packaging of supplies was observed to be placed under and inside the outer wrapping of the sterile chest-tube tray used to emergently insert a chest tube into the lung cavity of patients. By placing non-sterile packaging under the wrapper, the sterility of the surgical instruments inside the sterile tray was compromised.</p> <p>Staff #S91 was present during the tour. Interview with Staff #S91 confirmed that serial numbers were not being recorded and checked to ensure they had not been tampered with. Staff #91 confirmed that packaging of sterile items in the cart had been compromised due to method of storage in the cart. Hospital 2</p> <p>G. Environmental issues were observed to include unsafe storage of equipment and supplies, unsanitary conditions related to a cracked countertop and Pyxis medication storage, and improper disposal of trash.</p> <p>Findings:</p> <p>During a tour of the Post Anesthesia Care Unit at hospital #2 on 09/16/19 beginning at 1:30 p.m., accompanied by Staff #S205, Staff #S204, and Staff #S200, observations revealed an ice machine used for patients was sitting on a countertop with a crack to the back right side such that the countertop could not be properly cleaned.</p> <p>The above findings were confirmed during an interview of Staff #S200 in the PACU at hospital #2 on 09/16/19 at 2:00 p.m.</p>	A 724			



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A 724	Continued From page 256  During a tour of the clean supply warehouse at hospital #2 on 09/19/19 beginning at 11:10 a.m., accompanied by Staff #S222, Staff #S225, and Staff #S228, observations revealed the following:  1. A #20 fr foley catheter with a 5 cc balloon in a wrapper with black smudges draped over a dirty corrugated box and the finding was confirmed at the time of the observation by Staff #S225 and Staff #S222.  2. A pair of used exam gloves lying in a wire rack on a stored rolling cart used for patient care.  3. A pair of used exam gloves lying in a box with an item identified as a "CPR cable awaiting repair."  4. A "Let's Do This" orange bucket with multiple dirty blue rags with an orange peel on top of the rags.  5. A partially filled bottle of drinking water lying horizontal next to 1000 cc bags of 5% Dextrose in 0.45% Saline IV fluids - on the bottom of a cart with a cardboard box lying on top of one bag of the IV fluids and a plastic bin lying on 500 cc bag of 0.9% Sodium Chloride IV fluids.  The above findings were confirmed with Staff #S228 in an interview on 09/19/19 at 11:32 a.m., in the clean supply warehouse at hospital #2.  In an interview of Staff #S77 and Staff #S230 on 09/19/19 at 11:50 a.m., in the clean supply warehouse at hospital #2, both confirmed that	A 724			

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A 724	<p>Continued From page 257</p> <p>neither temperature or humidity were being monitored in the warehouse at the time of the survey.</p> <p>During an inspection of the Pyxis cabinet for the storage of medications in the sterile corridor of the operating suite at hospital #2 on 09/23/19 at 11:28 a.m., in the presence of Staff #S205, observation revealed dried drippage on the inside and outside of the clear plexi-glass door of the bottom shelf and areas of black debris to the lower shelf that could be removed from both areas by wiping them with an Oxivir wipe.</p> <p>In an interview on 09/23/19 at 11:28 a.m., in front of the Pyxis cabinet in the sterile corridor of the operating suite at hospital #2, Staff #S205 confirmed the above findings.</p> <p>The hospital policy no. 550.00 entitled, "Automated Dispensing Cabinets," with an effective date of "4/08," and a last review date of "08/27/2019," was reviewed on 09/24/19 at 1:58 p.m., in a conference room at hospital #2 and stated the following in part, "POLICY STATEMENT: The Automated Dispensing Cabinets (ADC) shall be used to increase patient safety, expedite medication administration, and ensure proper documentation of medication actions." The policy did not address the cleaning of the Pyxis.</p> <p>In an interview on 09/24/19 at 1:59 p.m., in a conference room at hospital #2, the Program Manager Accreditation, Regulatory Affairs, confirmed that the policy did not address cleaning</p>	A 724			

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A 724	Continued From page 258 of the Pyxis and that hospital does not have a policy on cleaning of the Pyxis.  In an interview on 09/24/19 at 9:33 a.m. ,in an administrative office at hospital #2, Staff #S498 confirmed that the hospital has nothing in a policy that addresses cleaning of the Pyxis machine for medication but stated, "Techs are encouraged on a daily basis to clean the Pyxis when they are delivering meds," "It's an expectation," and "Staff do monthly audits to check for expired meds. That is an opportunity to clean the Pyxis."	A 724			
A 747	<b>INFECTION CONTROL</b> CFR(s): 482.42  The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.  This <b>CONDITION</b> is not met as evidenced by: Based on review, observation, and interviews the facility failed to ensure the following:  A. Hospital #2 failed to ensure patient equipment (IV poles and IV pumps) was properly labeled, transported, inspected, and stored in a safe manner.  B. Hospital #2 failed to identify and label patient equipment used in isolation rooms and contaminated areas. Failed to ensure appropriate cleaning methods were performed to all soiled and contaminated patient equipment.	A 747			

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A 747	<p>Continued From page 259</p> <p>C. Hospital #2 failed to follow the facility's policy and procedures to prevent the spread of infections and provide a proper decontamination area to cleanse, sanitize, and store patient equipment.</p> <p>D. The Infection Control Preventionist (ICP) failed to monitor the appropriate use of disinfectant in the decontamination area, warehouse, telemonitor room, shared room, training, and oversight to the Central Supply Technicians and Environmental services for proper cleaning, sanitation, and storage of patient equipment. Hospital #2 failed to provide the technicians with proper personal protective equipment (PPE), adequate ventilation, Material Safety Data Sheet (MSDS) information, eye wash station, and hot water to cleanse the cleaning area and for proper hand hygiene.</p> <p>E. Hospital #2 failed to ensure that temperature and humidity were monitored in a clean supply warehouse where bags of IV fluids were stored.</p> <p>F. Hospital #2 failed to ensure that sterile and clean patient medical supplies were stored in a clean and sanitary environment in a temperature and humidity-controlled room in 3 (Supply warehouse, Central Supply, and Physical Therapy Department) of 3 areas observed.</p> <p>The condition and deficient practices were identified were determined to pose Immediate Jeopardy to patient health and safety and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>G. Hospital #2 failed to maintain a sanitary environment in the kitchen.</p>	A 747			

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A 747	Continued From page 260  H. Hospital #1 and #2 failed to maintain a sanitary environment in the physical therapy department. Hospital #2 Failed to properly sanitize the Fluid therapy machine between patients and no cleaning process was implemented. Hospital #1 failed to have documentation of the Hydroculator temperatures and failed to have clean linen available for patient use in the outpatient specialty clinic #4.  I. Hospital #1 failed to provide a clean and sanitary environment for patient areas 5G, 5F, and 3A.  J. Hospital #1 and #2 failed to properly isolate patients with infectious diseases by co-mingling patients in the same patient rooms.  K. Hospital #1 and #2 failed to ensure that tuberculosis skin tests (TST) given to employees as part of the infection control program were recorded with all information necessary to ensure that test results were accurate and/or correct.  L. Hospital #2 failed to keep separate clean items from dirty contaminated items including clean containers from soiled linens, to separate cleans beds from dirty beds, to keep clean patient supplies from touching the floors and/or being exposed to potentially dirty mops, and to ensure there was no blood or body fluids from being on the floor in a patient's room.  M. Hospital #1 failed to ensure a clean and sanitary environment in the occupational therapy room and 5 (4.214, 216,218,220, and 222) out 5 patient bathrooms in the mental health inpatient unit.	A 747			

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A 747	Continued From page 261  N. Hospital #2's Nursing staff failed to demonstrate appropriate hand hygiene and personal protective equipment (PPE) use when providing wound care to Patient # 405, and failed to demonstrate appropriate hand hygiene and proper disinfection of patient equipment when administering medication to Patient # 403.  O. Hospital #1 staff failed to perform hand hygiene before performing a interventional radiology procedure.  P. Hospital #1 failed to implement infection control practices of cleaning and disinfecting contaminated equipments. Failed to clean and disinfect Hansen connectors, wands, and all surfaces of contaminated hemodialysis machine in 2 of 2 hemodialysis machines observed terminally cleaned. Failed to wash/sanitize contaminated hands during central venous catheter care in 2 of 3 patients observed during termination of hemodialysis treatment. Patient #S16 and 15.  Q. Hospital #2's warehouse failed to ensure dialysis solutions were stored in a clean and temperature-controlled area.  R. Hospital #1 failed to ensure that manufacturer's directions regarding probe covers (sterile sheaths) were followed for use of endocavity transducers in the obstetrics clinic. Also, the facility failed to store the transvaginal probes per the manufacture guidelines.	A 747			
A 749	Refer to Tag A0749 INFECTION CONTROL PROGRAM	A 749			

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A 749	<p>Continued From page 262 CFR(s): 482.42(a)(1)</p> <p>The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.</p> <p>This STANDARD is not met as evidenced by: Based on review, observation, and interviews the facility failed to ensure the following:</p> <p>A. Hospital #2 failed to ensure patient equipment (IV poles and IV pumps) were properly labeled, transported, inspected, and stored in a safe manner.</p> <p>B. Hospital #2 failed to identify and label patient equipment used in isolation rooms and contaminated areas. Failed to ensure appropriate cleaning methods and proper disinfectants were performed to all soiled and contaminated patient equipment.</p> <p>C. Hospital #2 failed to follow the facility's policy and procedures to prevent the spread of infections and provide a proper decontamination area to cleanse, sanitize, and store patient equipment.</p> <p>D. The Infection Control Preventionist (ICP) failed to monitor the appropriate use of disinfectant in the decontamination area, warehouse, telemonitor room, shared room, training, and oversight of the Central Supply Technicians and Environmental services for proper cleaning, sanitation, and storage of patient equipment. Hospital #2 failed to provide the technicians with</p>	A 749			

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A 749	<p>Continued From page 263</p> <p>proper personal protective equipment (PPE), adequate ventilation, Material Safety Data Sheet (MSDS) information, eye wash station, and hot water to cleanse the cleaning area and for proper hand hygiene.</p> <p>E. Hospital #2 failed to provide a sanitary environment because temperature and humidity were not monitored in a clean supply warehouse where bags of IV fluids were stored next to a partially filled bottle of drinking water, a Foley catheter was draped over a dirty corrugated box, a bucket held dirty rags and orange peels, and used exam gloves had not been disposed of properly.</p> <p>F. Hospital #2 failed to provide a clean and sanitary environment to mitigate the risks of possible hospital acquired infections and ensure sterile and clean patient medical supplies were stored in a clean and sanitary environment in a temperature and humidity-controlled room in 3 (Supply warehouse, Central Supply, and Physical Therapy Department) of 3 areas observed.</p> <p>The condition and deficient practices were identified were determined to pose Immediate Jeopardy to patient health and safety and placed all patients at risk for the likelihood of harm, serious injury, and possibly subsequent death.</p> <p>G. Hospital #2 failed to maintain a sanitary environment in the kitchen.</p> <p>H. Hospital #1 and #2 failed to maintain a sanitary environment in the physical therapy department. Hospital #2 failed to properly sanitize the Fluid therapy machine between patients and no cleaning process was implemented. Hospital #1</p>	A 749			



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A 749	<p>Continued From page 264</p> <p>failed to have documentation of the Hydroculator temperatures and failed to have clean linen available for patient use in the outpatient specialty clinic #4.</p> <p>I. Hospital #1 failed to provide a clean and sanitary environment for patient areas 5G, 5F, and 3A.</p> <p>J. Hospital #1 and #2 failed to properly isolate patients with infectious diseases by co-mingling patients in the same patient rooms.</p> <p>K. Hospital #1 and #2 failed to ensure that tuberculosis skin tests (TST) given to employees as part of the infection control program were recorded with all information necessary to ensure that test results were accurate and/or correct.</p> <p>L. Hospital #2 failed to keep separate clean items from dirty contaminated items including clean containers from soiled linens, to separate cleans beds from dirty beds, to keep clean patient supplies from touching the floors and/or being exposed to potentially dirty mops, and to ensure there was no blood or body fluids from being on the floor in a patient's room.</p> <p>M. Hospital #1 failed to ensure a clean and sanitary environment in the occupational therapy room and 5 (4.214, 216,218,220, and 222) out 5 patient bathrooms in the mental health inpatient unit.</p> <p>N. Hospital #2's Nursing staff failed to demonstrate appropriate hand hygiene and personal protective equipment (PPE) use when providing wound care to Patient # 405; failed to demonstrate appropriate hand hygiene and</p>	A 749			

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A 749	<p>Continued From page 265</p> <p>proper disinfection of patient equipment when administering medication to Patient # 403.</p> <p>O. Hospital #1 failed to perform hand hygiene before performing a interventional radiology procedure.</p> <p>P. Hospital #1 failed to implement infection control practices of cleaning and disinfecting contaminated equipment. Failed to clean and disinfect Hansen connectors, wands, and all surfaces of contaminated hemodialysis machine in 2 of 2 hemodialysis machines observed terminally cleaned. Failed to wash/sanitize contaminated hands during central venous catheter care in 2 of 3 patients observed during termination of hemodialysis treatment. Patient #S16 and 15.</p> <p>Q. Hospital #2's warehouse failed to ensure dialysis solutions were stored in a clean and temperature-controlled area.</p> <p>R. Hospital #1 failed to ensure that manufacturer's directions regarding probe covers (sterile sheaths) were followed for use of endocavity transducers in the obstetrics clinic. Also, the facility failed to store the transvaginal probes per the manufacture guidelines.</p> <p>Decontamination Room Hospital #2</p> <p>A tour of the Decontamination Room was conducted on the morning of 09/19/2019, with Staff #S272. The Decontamination room was approximately 12 ft by 10 ft and had 7 cracked visibly soiled tiles on the floor with an elongated rectangular drain in the middle of the room that</p>	A 749			

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A 749	<p>Continued From page 266</p> <p>was rusted, making it impossible to clean. A dirty crash cart was located in the room with an employee's jacket laying on top of it. A shelf located on the back wall of the room housed a visibly soiled sterile package containing an infant chest tube from 2003.</p> <p>15 dirty IV poles were present with rust on the base of each pole. Staff #S272 reported, the IV poles had been placed there "sometime last week". One of the IV pumps had a clear plastic bag partially wrapped around it. Staff #S272 reports that IV pumps wrapped in plastic bags are from patient isolation room. However, the technician was unable to identify what type of isolation room or infectious disease the IV pump had come in contact with, making proper sanitation of the equipment impossible.</p> <p>A dirty crash cart was in the room with a jacket laying on top of it. A shelf located on the back wall of the room housed a visibly soiled sterile package containing an infant chest tube from 2003.</p> <p>The room contained a place for gloves, but no other Personal Protective Equipment was available for staff use.</p> <p>The decontamination process was conducted on a stainless-steel surface next to a sink. The sink did not have hot water and had hardwater build up around the faucet. Once the contaminated patient equipment was clean it was placed back on the dirty surface area. The equipment was then wrapped and placed on a dirty linen basket.</p> <p>Staff #S272 reported that she has never received infection control training that pertains to the</p>	A 749			

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A 749	<p>Continued From page 267 disinfection of patient equipment.</p> <p>Staff #S322 confirms the findings in an interview when she states, "I would use the new decontamination room myself. I had never seen the old room".</p> <p>Warehouse Hospital #2</p> <p>A tour was conducted of the facility's warehouse with Staff #S222 and Staff #S227 on 9/17/19 at approximately 12:45 PM. The warehouse had multiple loading and unloading areas. The warehouse was entered from a door that was unlocked. On one wall of the warehouse, there was three garage doors with 2 doors that were currently opened.</p> <p>The following observations were found:</p> <p>The concrete floors were heavily soiled with clumps of dirt, dust, paper trash, bird feathers, and insects.</p> <p>Heavily soiled cardboard boxes and plastic tubs of patient medical supplies were sitting on soiled metal carts ready to be transported to the hospital uncovered. Two of the heavily soiled metal carts had staff food sitting on them.</p> <p>There was no dirty to clean areas marked out in the warehouse.</p> <p>Patient sterile and clean medical supplies were found uncovered sitting next to shipping boxes, sitting on the floor on wooden pallets, and heavily soiled metal cart with heavy dust and dirt around the supplies. Sterile and clean medical supplies</p>	A 749			

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A 749	<p>Continued From page 268</p> <p>were also seen lying on the floor of the warehouse. Some of the sterile items observed throughout the Warehouse exposed to environmental contaminants included:</p> <ul style="list-style-type: none"> <li>*Paracentesis kit</li> <li>*Urinary Catheter kit</li> <li>*Dry Suction Water Seal Chest Drain kit</li> <li>*1 box of Chloraprep- preoperative skin preparation</li> </ul> <p>Multiple types of opened and exposed patient supplies were sitting on dusty and dirty pallets. Multiple patient IV bags were sitting in an opened soiled storage containers, also sitting on heavily soiled metal carts.</p> <p>Patient exercise equipment was seen in the warehouse with heavily soiled moving blankets placed on top of the equipment. A dirty patient treadmill with trash, soiled cords, and an orange cone sitting on top of it was sitting in the warehouse uncovered.</p> <p>50 + unmarked patient beds were being stored in the Warehouse. Staff #S227 was unable to verify if the beds were broken. There were no signs indicating if the beds were clean or dirty.</p> <p>An interview with Staff #S222 was conducted on the morning of 9/17/19. Staff #S222 reported that the doors to the warehouse could be open for long lengths of time. The warehouse stored laboratory equipment and surgical supplies that were required to be in temperature and humidity-controlled areas. Staff #S222 confirmed, there had been no tracking of temperatures or humidity within the warehouse area. Staff #S222 was asked if he had ever had any infection control training and he replied, "no, I have not."</p>	A 749			

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A 749	Continued From page 269  Telemonitor Room Hospital #2  A tour of Hospital #2's Telemonitor Room was conducted on the morning of 09/26/2019. Along the entrance wall the room housed a table for decontamination of individual telemonitors. Staff #S755 demonstrated the process for sanitizing telemonitors. The table contained a box of dirty monitors that sat next to a "Huck" or waterproof barrier. One type of disinfecting wipes was sitting on the waterproof barrier next to the dirty monitor, exposing the wipes to contaminants. There were no other types of disinfectants available. Clean monitor storage was on the same table next to the waterproof barrier and dirty telemonitors. The staff member was unable to identify what type of isolation room or infectious disease the telemonitor had been exposed to, the use of appropriate disinfectant to sanitize patient's telemonitors was not known.  There was one box of gloves on the table sitting a waterproof barrier. There was no other personal protective equipment available for staff use and the room did not contain a place for staff members to wash their hands. There was a red biohazard trash can on the floor.  The decontamination process was conducted on the waterproof barrier. The stored dirty equipment was sitting next to the cleaning area in a plastic tub. The visibly soiled and contaminated telemonitors were placed on the waterproof barrier and once it was cleaned, the now clean telemonitors was placed back on the same dirty surface area and allowed to dry. The telemonitor sitting on the contaminated waterproof barrier is	A 749			

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A 749	<p>Continued From page 270</p> <p>then placed in storage bins on the same table or in plastic Ziploc bags to be sent to the unit for patient use. The technician was unaware that she had just placed a clean item on the contaminated waterproof barrier. The patient telemonitors were now potentially exposed to infectious organism and contaminated, the telemonitor would be sent to the units for patient use.</p> <p>The facility-based policy "Centralized Telemetry Monitoring" reviewed on 9/26/2019 stated in part, "C. Telemetry Box Removal: ... 3. The nurse or PCA cleans the telemetry box and cardiac leads and places the telemetry box and cardiac leads in a Ziploc bag and return to the Central Telemetry Monitoring Center. 4. The telemetry-monitoring technician documents the return of the telemetry box and cardiac leads. 5. The telemetry-monitoring technician cleans the telemetry box and cardiac leads with recommended bactericidal solution for future use ..."</p> <p>Shared-Patient Rooms Hospital #2</p> <p>A review of clinical records for unit 3A was conducted on the afternoon of 9/17/2019 with Staff #S265 and revealed the following:</p> <p>*Patient #81 with a wound on the left thigh that had a confirmed diagnosis of penicillin resistant Staph Aureus was placed in a shared room with Patient #82 being treated for an asthma exacerbation.</p> <p>A tour was conducted with Staff #322 on Unit 4C</p>	A 749			

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A 749	<p>Continued From page 271</p> <p>to observe patients #85 and #86 who were in a shared room on the morning of 9/18/19. There was hair on the shower floor and unidentified wet substance visible on the bathroom ground. The bathroom shower had cracked tiles with missing grout, making it impossible to disinfect and prevent the spread of infectious diseases.</p> <p>In an interview with Staff #S322, she reported that patients who have a known infectious disease may share a room with other patients as long as the infectious disease is "contained." Staff #S322 further explained by stating, "patients who have a wound that is covered or a urinary infectious disease with a catheter would be considered contained." When asked where the catheter is disposed of she stated, "in the patient's (shared) bathroom." Staff #S322 further reported, there is no policy or procedure instructing unit staff to clean the bathroom between patient use or disposal of bodily fluids containing infectious disease in the shared bathroom exposing patients to possible infectious diseases.</p> <p>Hospital #2</p> <p>During a tour of the clean supply warehouse at Hospital #2 on 09/19/19 beginning at 11:10 a.m., accompanied by Staff #S222, Staff #S225, and Staff #S228, observations revealed the following:</p> <ol style="list-style-type: none"> <li>1. A #20 fr Foley catheter with a 5 cc balloon in a wrapper with black smudges draped over a dirty corrugated box and the finding was confirmed at the time of the observation by Staff #S225 and Staff #S222.</li> <li>2. A pair of used exam gloves lying in a wire rack on a stored rolling cart used for patient care.</li> </ol>	A 749			



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A 749	<p>Continued From page 272</p> <p>3. A pair of used exam gloves lying in a box with an item identified as a "CPR cable awaiting repair."</p> <p>4. A "Let's Do This" orange bucket with multiple dirty blue rags with an orange peel on top of the rags.</p> <p>5. A partially filled bottle of drinking water lying horizontal next to 1000 cc bags of 5% Dextrose in 0.45% Saline IV fluids - on the bottom of a cart with a cardboard box lying on top of one bag of the IV fluids and a plastic bin lying on top of a 500 cc bag of 0.9% Sodium Chloride IV fluids.</p> <p>The above findings were confirmed with Staff #S228 in an interview on 09/19/19 at 11:32 a.m. in the clean supply warehouse at Hospital #2.</p> <p>In an interview of Staff #S77 and Staff #S230 on 09/19/19 at 11:50 a.m., in the clean supply warehouse at hospital #2, both confirmed that neither temperature or humidity were being monitored in the warehouse at the time of the survey.</p> <p>Hospital #2</p> <p>1. An observation tour was conducted on 9/19/2019 after 11:00 AM, with Staff #S205, #S227, #S224 in the supply warehouse. This is a large warehouse where most all supplies for Harris Health are delivered. There are two large doors to the left that roll up and down for deliveries. To the right was rows of shelves and pallets covered with shipping boxes and blue shipping bins. Upon inspection of these boxes</p>	A 749			

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A 749	Continued From page 273 and bins, the following were found:  A. A sterile Cross-Cut Carb Bur, (a rotary cutting tool used in surgical procedures) was found in an open shipping box.  B. A blue shipping bin with sterile surgical gowns, sterile gloves, and sterile infant catheters that was left open and exposed to unmonitored temperatures and humidity's.  C. Lying on a pallet was a sterile Dry Suction Water Seal Chest Drainage System that was heavily soiled with dirt and dust.  D. Next to the sterile water seal chest drainage system were several half opened boxes of Similac Neosure (a formula used to feed preterm infants) exposed to unmonitored temperatures.  E. A blue shipping bin with two sterile tracheostomy care set trays and a sterile surgical gown. The blue bin was visibly dirt with dust and dirt and open to the temperature of the room.  D. Two sterile Pericardiocentesis Kits we found on top of two blue shipping bins. One sterile kit was found to have a hole in the outer plastic exposing the sterile items to dirt, dust, and debris.  E. Two opened shipping boxes containing approximately 12 bottles of 1 inch sterile packing strip (sterile packing used for wounds) were covered with dust and dirt.  F. The floor near the loading dock was visibly wet due to rain, and delivered boxes were sitting on the wet concrete.	A 749			

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A 749	<p>Continued From page 274</p> <p>An interview was conducted on 9/19/2019 after 11:00 AM, with Staff #S227. S227 was asked if all the boxes were delivered today. Staff #S227 replied, "No they were not all delivered today. The ones over there on the pallets could have been here several days and just not delivered to the department yet. We will go and stock the departments ourselves mostly, but we do not stock the OR department. We take their stuff up on the service elevator to the 4th floor and they come and unbox it and stock it themselves."</p> <p>A review of the document titled, "PRE-CLEANNING, STERILIZATION, HIGH AND LOW LEVEL DISINFECTION, AND STORAGE OF PROCESSED PATIENT DEVICES, APPENDIX N STERILE ITEMS, Policy No: 1301 effective Date: 12/16" revealed:</p> <p>"...A. Sterile items should be stored in manner that will reduce the potential for contamination:</p> <ol style="list-style-type: none"> <li>1. Room temperature should be approximately 24 Degrees C (75 degrees F)</li> <li>2. The room (s) should have at least for (4) air exchanges per hour, and</li> <li>3. Humidity should be controlled so that it does not exceed seventy percent (70%).</li> </ol> <p>G. Outside shipping containers, (corrugated cardboard cartons) should not be used as containers in sterile storage areas..."</p> <p>Staff #S227 confirmed the above findings.</p>	A 749		

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A 749	Continued From page 275  2. An observation tour was conducted in the Central Supply on 9/19/2019 after 10:00 am, with Staff #S205, #S227, and #S227. This room was used to store clean patient equipment and supplies to restock the crash-carts (a multi drawer cart that stores patient supplies readily available for use in an emergency) within the hospital. Upon entering the room, there were multiple carts, open shelves storing sterile and non-sterile supplies, closed cabinets storing patient supplies, and clean equipment placed along the wall.  An interview was conducted with Staff #S227 on 9/19/2019 after 10:00 AM. Staff #S227 was asked what all was stored in this room. Staff #S227 stated, "It is supplies to replace crash cart items and take-home supplies for the patients if they need them." Inside the Central Supply room there were multiple carts with dirty biohazard bins (red bins used to discard needles and sharp objects) attached to the sides. Down the left side of the room were several closed cabinets. Inside the closed cabinets were patient supplies with corrugated boxes just lying on top of the supplies.  In the first cabinet, there was a corrugated box stored on top of Aquacel Extra (an antimicrobial used in the treatment of wounds on patients). Inside the cabinet labeled "Cabinet-8" was dirty corrugated shipping boxes next to a sterile instrument set wrapped in plastic. Staff #S227 was asked why the sterile instrument set was sitting on the bottom shelf next to a soiled external shipping box. Staff #S227 replied, "That's an old set of instruments in a large tray	A 749			

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A 749	<p>Continued From page 276</p> <p>that we don't put on the crash carts any more. We should have sent that to sterile processing because now they are wrapped and stored different."</p> <p>Inside the cabinet labeled "Cabinet-6 were multiple blue bins used to store anti-embolism stockings. The blue bins were heavily soiled with dirt, dust, and debris. Inside Cabinet-7 was multiple boxes of Aquacel Extra stored on a shelf that had missing paint and chipped surface exposing the porous wood underneath. The porous surface cannot be sanitized to mitigate the risk of hospital acquired infections. On top of the Aquacel Extra boxes were 2 corrugated boxes that were covered with dirt and dust.</p> <p>Along the back wall were 4 IV poles with IV pumps attached. These were being charged through an electrical outlet along the wall. The bottom of the IV poles were rusted, chipped, and missing paint. Rusted surfaces cannot be properly sanitized. A metal shelf was seen storing corrugated and external shipping boxes heavily covered with dust and dirt.</p> <p>Staff #S227 and #S224 confirmed the above findings.</p> <p>A review of ANSI/AAMI ST79:2017 revealed the following:</p> <p>"11.1 Sterile Storage</p> <p>Sterile items should be stored under environmentally controlled condition that reduces the potential for contamination ...</p>	A 749			

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A 749	<p>Continued From page 277</p> <p>Supplies should be removed from external and web-edged shipping container before transport to any restricted area ..."</p> <p>3. A tour of the Physical Therapy Department was conducted on 9/17/2019 after 1:30 PM, with Staff #S205. Upon entering the department, the surveyor saw a patient stretcher parked in the hall way next to the wall. Upon further inspection it was noted that the sign on the door read two doctor's names. The door was open and four patient stretchers were stored. Staff #S205 was asked why the stretchers were stored in this room and if they were cleaned prior to being placed here. Staff #S205 stated, "We don't have any storage place to keep them and we will just come and get one if we need it. No, I do not know if they are clean or not."</p> <p>There were two additional rooms labeled with doctor's names with patient stretchers. There was a total of 12 stretchers stored in three rooms that were unclean. Staff #S205 was asked why the stretchers were being stored in a room that was not identified as a supply room. As she began to remove the signs she stated, "Because they are behind on making signs for doors. These stretchers are not only for the OR, they are also stretchers used in the emergency room, and labor and delivery. So, they bring them here too." Staff #SS205 was again asked if the stretchers were cleaned before they were brought to this department for storage. Staff #S205 stated, "I do not know if they are clean or not. I cannot say for sure that they are clean."</p> <p>Staff #S205 confirmed the above findings.</p>	A 749			

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A 749	Continued From page 278  A tour was conducted of the kitchen at Hospital #2, in the morning of 9/16/19, with staff #S73, S74, S76, and S77.  Hospital #2 - Kitchen  The retail refrigerated shelving unit was found to have rusted areas where food is stored and sold.  The main ice machine in the kitchen area was found to have mold and mildew on the inside lid. #S73 reported the ice machine was on a cleaning schedule but confirmed the findings of the mildew, and confirmed it was not cleaned properly.  The dish washing area had missing and broken floor tiles. Food particles were found down in the broken tiles making it difficult to keep clean.  Two of the door jams and threshold in the kitchen were soiled, missing paint, and dirty.  The dishwasher was dirty and caked up with grime in the door facing area.  9 plastic cases with snap lids were found stacked on a metal cart. The cases were full of condiments for patient use. The cases were soiled and sticky on the inside and condiments had spilled on the contents inside.  The ice cream freezer was soiled on the inside with trash and dried food particles. The sides of the freezer had significant ice buildup. The freezer was unable to be wiped down and cleaned properly due to the ice buildup.	A 749			

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A 749	Continued From page 279  Grout was missing between multiple tiles in the kitchen food prep areas. Food particles and debris was found in the missing grout areas. The floor could not be properly cleaned.  5 large packages of ground meet were found on 9/16/19 in the refrigerator section. The meat had a received date of 9/13/19. There was no date on the meat on when it was to expire. The kitchen staff was unable to provide any guidelines or information on how long the meat could be refrigerated before use. The kitchen staff was unable to guarantee safety of the meat. #S77 had the meat discarded.  2 plastic containers were found on a shelf in the cooler. #S73 confirmed they were used to place food in. The lids were removed, and the plastic cooler was soiled on the inside with dirt.  a container holding sugar was found to have a soiled scooper sitting inside the bin. The scooper was soiled with spilled dried reddish orange liquid.  A plastic three-tiered food cart was observed sitting in the kitchen next to the food prep area. The cart had lettuce in a container sitting on the cart. The cart was soiled with trash, dried spilled liquids, and dried food particles.  A six-layer metal cart was found in the cooler with a plastic bag over it. Inside the cart was trays of homemade pizzas. There were multiple stickers on the cart with different dates of when the pizzas were made. One of the stickers said 9/13/19, another stated 9/16/19 and 9/14/19. The spinach on the pizza was dried out and crunchy. The staff	A 749			



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A 749	<p>Continued From page 280</p> <p>could not guarantee when the pizzas were made or when they should expire. The pizzas had to be discarded.</p> <p>The dish warmer was found sitting next to the serving line. It was full of dishes to use for patient trays. The inside and rim of the dish warmer was soiled with dried food particles and dried liquids.</p> <p>24 cups were found ready for use stacked on a shelf. The cups were wet and trash was found under the cups.</p> <p>A large stack of patient food trays was stacked and placed on the line for food. 10 trays were pulled from the stack. All the trays were wet and dripping water. The trays had not been allowed to properly dry before stacking.</p> <p>3 cooking sheets were found wet, ready for use with heavy carbon build up around the bottom and sides. The sheets are not able to be cleaned properly and the surveyor was able to remove the carbon residue off with a finger.</p> <p>4 large cooking pans were found stacked wet and ready for use.</p> <p>12 medium and small metal pans were found stacked wet and ready for use.</p> <p>Stacking wet dishes, pots, or pans without completely drying first, provides a moist, warm environment which provides good conditions for bacterial growth. This is called wet nesting. The FDA 2017 specifies that all dishes should be air-dried before being stacked and stored. The code states, "Items must be allowed to drain and to air-dry before being stacked or stored.</p>	A 749			

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A 749	<p>Continued From page 281</p> <p>Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow."</p> <p>An interview with #S73 was conducted on 9/16/19. #S73 confirmed there was inadequate drying area for the size of the kitchen and the staff were stacking wet dishes when they needed more room.</p> <p>A tour was conducted of the Physical Therapy (PT) Department at Hospital #2, in the morning of 9/17/19, with the director of therapy services for Hospital #2.</p> <p>Hospital #2- Physical Therapy</p> <p>The wall behind a hand washing sink and paper towel holder had been patched but had not painted or sealed. The sheet rock was still porous and unable to be cleaned from splattered water from the sink.</p> <p>A door leading out to the patio and playground was missing molding. Sheet rock was chipped and missing around the threshold.</p> <p>A wooden stand up mirror was found to be worn on the legs. The wood was now porous and unable to be cleaned appropriately.</p> <p>A small freezer used for cold packs was found to have excess ice buildup on the inside. Two blue plastic cups were found in the freezer and were found to be soiled with unidentifiable substance. The freezer was unable to be cleaned properly</p>	A 749			

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A 749	<p>Continued From page 282 due to ice buildup.</p> <p>The paraffin wax machine is used for patients to dip their hands in. The inside bottom of the wax was soiled. There was no Preventative Maintenance (PM) sticker on the outside yet this was an item that must be plugged in and can cause injury to a patient if it is not working properly.</p> <p>The splint form tray was soiled with mineral build up and rusted areas.</p> <p>A Fluidotherapy machine was not included in the cleaning schedules for infection prevention. The PT director confirmed the machine was not being cleaned and did not have any information available in how the machine should be cleaned. Fluidotherapy is a medical treatment using a Fluidotherapy unit that creates a dry thermal heated air streaming and flowing through and over finely granulated Cellex particles in a chamber. The patient places their hands and arms down into the unit.</p> <p>Hospital #2 - Executive Nursing Area</p> <p>During chart reviews on 9/18/19, room #250 had rain dripping from the ceiling and around the windows. The sheet rock had opened and mold and mildew were found in the ceiling.</p> <p>A tour was conducted of the Central Supply Room #1, #2, and warehouse on the morning of 9/19/19 at 10:10 AM.</p>	A 749		

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A 749	<p>Continued From page 283</p> <p>Hospital #2 - Central Supply Room</p> <p>The central supply room was found to have opened patient medical supplies stored with dirty shipping boxes, dirty crash carts, and soiled hospital equipment.</p> <p>Opened patient medical supplies were found stored with dirty shipping boxes, dirty crash carts, and soiled hospital equipment.</p> <p>Soiled crash carts were found with sharps containers attached. The sharps containers had dirty syringes and tubing inside.</p> <p>Multiple surgical instruments were found in boxes laying open.</p> <p>Rusted patient IV poles and pumps were found sitting next to clean patient medical supplies.</p> <p>Hospital #2 - Clean Supply Room #2</p> <p>A clean patient supply room was found behind the main central supply area. The room had opened medical supplies sitting on metal racks. Dirty Oxygen bottles were sitting in heavily soiled and rusted racks.</p> <p>A bin of surgical tape was found covered in a gritty rusted particles and dirt. Shipping boxes were mixed in with the open supplies.</p> <p>Hospital #2 - Warehouse</p> <p>A warehouse was found with two bay doors open during a heavy rain storm. There was no</p>	A 749		

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A 749	<p>Continued From page 284</p> <p>distinction or areas marked off to determine what areas were considered dirty, clean, and ready to go out to patients. The warehouse serves both Hospitals #1 and #2, and out patients areas.</p> <p>An interview with #S227 confirmed there was no dirty, to clean, to patient process in the warehouse. #S227 stated, "All of the warehouse is considered clean."</p> <p>Rain was blowing into the warehouse getting packages soiled with rain water. The concrete floor was wet and patient supplies were sitting on the wet floor.</p> <p>Blue bins that come from a supplier with patient supplies in them. When they are emptied the boxes go back for more supplies. The boxes were heavily soiled and sitting in soiled areas. There was no information on how these boxes are cleaned.</p> <p>#S227 reported that he was not sure how the blue bins were cleaned when they left his facility. #S227 stated, "I used to work for them before I came to work here. We used to just wash them out with a water hose, but I don't know what they do now."</p> <p>The blue boxes had mix matched supplies in them with no indication what was in the boxes. The boxes were stacked all over the warehouse with no clear process to unload and deliver where needed.</p> <p>Over 50 cardboard shipping boxes were found on the ground opened with patient supplies inside. Some of the boxes were found on the ground or on wooden pallets. The boxes were dusty and</p>	A 749			

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A 749	<p>Continued From page 285</p> <p>dirty along with the supplies inside.</p> <p>Multiple beds were stored in the warehouse and had plastic over them. The beds were supposed to be clean. The beds were stored in a heavily soiled and dirty warehouse. No cleaning instructions were found or offered.</p> <p>A refrigerated area was found in the soiled warehouse. Inside was laboratory agents. The inside of the refrigerated unit was heavily soiled with dirt and the door gasket was broken and soiled with mildew.</p> <p>A box of surgical CloraPreps (a sterile product) was found wet, sitting on a pallet, opened and exposed to elements and dirt.</p> <p>10 of the blue boxes were found open with multiple supplies in the boxes. Patient IV fluids were found in the boxes along with sterile suture remover sets, bandages and syringes. The bags of D5 IV fluids were found with dust and dirt on them.</p> <p>7 Foley catheter trays were found unboxed sitting on top of other soiled shipping boxes. The trays were dirty.</p> <p>A sterile surgical pack was found sitting on a dirty wooden pallet. The covering of the pack was ripped and dirty. Inside the pack was surgical drapes and equipment.</p> <p>The floors of the warehouse were littered with trash, dirt, hair, and wood chips. The concrete flooring had large cracks and holes making it difficult to properly clean.</p>	A 749			

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A 749	<p>Continued From page 286</p> <p>A box of 24 liquid contrast bottles, that is consumed by the patient, was found sitting in an opened box and on the soiled floor. T-connector extension sets were found lying open and exposed to dirt and dust.</p> <p>An interview was conducted with #S332 on the morning of 9/19/19. #S332 confirmed that she had never been in the warehouse and had never done rounds for infection control or monitor the clean handling and storage of patient medical supplies.</p> <p>Review of the facility policy number 5000 titled "Infection Prevention Guidelines in Rehabilitation Services &amp; Child Life" stated in part, "I. Procedure:</p> <p>...E. Hydrocollator</p> <p>1. Water temperature is recorded daily on the infection control log.</p> <p>2. To insure patient safety, the hot pack water temperature range is one hundred fifty degrees (150°) to one hundred seventy degrees (170°) F ...</p> <p>4. Cleaning:</p> <p>a. Once a month, hot packs and racks are removed.</p> <p>b. The water in the tank is drained and the inside is wiped with sponge, cloth or cleaning pad with a mild soap ..."</p>	A 749		

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A 749	<p>Continued From page 287</p> <p>Facility form titled "DAILY - Infection Control Schedule Log" stated in part, "Area: Hydrocollator; Record Temperature ... Temperature 150°F-170°F. Per HHS Policy #5000."</p> <p>During the tour on 9/16/19 at 2:20 PM, the AM and PM checks for the past six months had initials indicating these had been checked but had no information regarding the temperatures at those times.</p> <p>The bottom column of the form had no area or task indicated but was signed off as being checked each day.</p> <p>Facility form titled "Monthly - Infection Control Schedule Log" for August 2019 indicated the areas, "equipment/area; hot pack covers, hydrocollator, monthly safety rounds" were left blank and not documented as completed.</p> <p>In an interview with staff #S582 on 9/16/19 at 2:20 PM, when asked if they checked and recorded the temperature on the hydrocollator, they stated, "I check it every day ... I initial that it's in range."</p> <p>The above was confirmed in an interview with staff #S121 on 9/18/19 at 10:45 am.</p> <p>Tour of the Out Patient Specialty Clinic #4 on 9/23/19 at 10:35 am, revealed, linen was stored contained a shipping box, overhead lights with dead bugs, and clean linens with a torn plastic</p>	A 749			



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OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>450289</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>09/27/2019</b>
NAME OF PROVIDER OR SUPPLIER  <b>HARRIS HEALTH SYSTEM</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>2525 HOLLY HALL HOUSTON, TX 77054</b>		
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A 749	<p>Continued From page 288 covering.</p> <p>The above was verified on the tour on 9/23/19 at 10:35 am with staff #S591.</p> <p>A tour of Hospital 1: Unit 5F and 5F was conducted the morning of 9/16/19, accompanied by Staff #S62, #S63, and #S64, the following was observed:</p> <p>In the nourishment room, there were drips, stains, and dirt on the doors and the base of the cabinet where including styrofoam cups and lids were stored for use in patient care.</p> <p>The ice machine had a layer of what appeared to be rust on the underside of the dispenser.</p> <p>In the 5G medication room, there was raised dirt and debris on the floors around the baseboard and around and behind equipment, indicating a need for thorough cleaning. The sink in the medication room had a object that looked like a rusted wire or rusty "worm" in the drain which Staff #S64 stated had been there a long time. The cabinet under the sink was closed with a zip tie. When staff cut the zip tie and opened the doors, the inside and floor of the cabinet was observed to be dirty and covered with a raised level of dust and dirt.</p> <p>In the 5F medication room, the cabinet under the sink was dirty with raised dirt and debris and 2 areas that appeared to be from old water leaks.</p> <p>In the environmental services supply room, there were 2 spray cleaning bottles partially filled with a liquid that were not labeled as to contents or expiration date. There was no means to</p>	A 749			

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A 749	<p>Continued From page 289</p> <p>determine the contents of the bottle and whether they contained materials that needed special handling. The floor and horizontal surfaces in the room were dirty and dusty. A dust mop coated in dust was hanging on the wall above and over cleaning supplies and a mop bucket.</p> <p>In quad patient room 5G02-4, the bathroom was shared by 4 patients. In the bathroom, at 11:23 am, there were dirty towels on the floor. This presents an infection control risk with a shared bathroom. Also, at 11:40 am, there was a urinal about 1/4 full of a brownish-yellow liquid sitting on the side of the bathtub in the shared quad room.</p> <p>These findings were confirmed in an interview with Staff #S62, #S63, and #S64 during the tour the morning of 9/16/19.</p> <p>A tour of Hospital 1, Unit 3A was conducted the morning of 9/17/19 accompanied by Staff #S62 and #S145, the following was observed:</p> <p>An EKG machine was observed in use which had a black sticky substance on the handle of the cart next to the keyboard used by the nurse. There were opened EKG leads in the drawer. This presents a risk for cross contamination.</p> <p>In the clean supply room, the cabinet under the sink was dirty, with old dried drips in the base of the cabinet and debris on the cabinet floor.</p> <p>In patient room 3A 1-1, a shared patient room, there were dirty wet towels and a dirty patient gown in the bathroom, hanging on the towel rack next to the sink. There were 2 used EKG leads stuck to the handicap bar in the patient shower.</p>	A 749			

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A 749	<p>Continued From page 290</p> <p>The above findings were confirmed in an interview with Staff #S62 and S145 during the tour the morning of 9/16/19.</p> <p>Findings:</p> <p>1) Review of patient list "5B Med/Surg- Last Refreshed: 09/18/19 0944," reflected Patient #70 in room 5B02/01 and Patient #69 in room 5B02/02. These two patients were in a shared room with a shared bathroom. "Isolation" column on this list reflected neither of these two patients were identified as requiring contact precautions. However, "Infection" column reflected Patient #69 had "Klebsiella pneumonia MDR (multiple drug resistant)."</p> <p>Review of Patient #69's medical records reflected, he arrived at Hospital #1's Emergency Department on 9/16/19 and admitted to room 5B02 on the same day:</p> <ul style="list-style-type: none"> <li>- H&amp;P (History and Physical) Notes dated 9/16/19, reflected a "67 y.o. male ... with h/o (history of) ... UTI (Urinary Tract Infection) in March, June, and July 2019 with ESBL (Extended spectrum beta-lactamase) Klebsiella + urine cx (culture) ..."</li> <li>- "General Infectious Disease Consult Service, Progress Note" on 9/18/19, by Staff S699, reflected reason for consult as "h/o ESBL Klebsiella pneumoniae UTI, recurrent infection ..."</li> <li>- Urine Culture resulted on 9/19/19, reflected abnormal results with lab value of "&gt;100,000</li> </ul>	A 749			

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A 749	<p>Continued From page 291</p> <p>CFU/ml ESBL producing Klebsiella pneumoniae."</p> <p>- Patient teaching notes on topic of Infection reflected "NR (Needs Reinforcement)" on 9/19/19 and 9/20/19.</p> <p>- Patient teaching notes (under Infection Prevention) on topics of Hand Hygiene, Contact Precautions, and Multi-Drug Resistant Organisms reflected "NR" on 9/19/19 and 9/20/19.</p> <p>In an interview on 9/20/19, at 10:47 a.m., Staff #S118 stated, "we have dedicated isolation rooms (in Emergency Department) for Contact, Droplet, and Airborne precaution patients. We never put such patient in shared rooms."</p> <p>During an observation on 9/20/19, at 2:44 p.m., Patient #69 was in room 5B02/02 and Patient #70 in room 5B02/01. There was no signage/posting on room 5B02 indicating a need for "Contact Precautions."</p> <p>Review of Isolation Sign (Signage) used by the unit reflected for "Multiple Drug Resistant Organisms (found in bodily fluids)," contact isolation was required in Non-ICU units if "(bodily fluid) not contained or if patient is incoherent." Additionally, "Isolation precautions must be used for: suspected, previous positive and current + MDRO."</p> <p>In an interview on 9/20/19, at 2:44 p.m., Staff S367 stated, if a patient (with infection of ESBL with Klebsiella in urine) is fully alert and oriented,</p>	A 749			

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A 749	<p>Continued From page 292</p> <p>then this patient is placed in a shared room with other patient (not necessarily with patient with same infection). If patient is not fully alert and oriented, then this patient is placed in a single isolation room. Patient #69 is fully alert and oriented, and used the bathroom independently. Staff S52 stated, we would place these patients (with positive ESBL in urine, unless patient had a Foley catheter [to contain urine]) in a single room, but due to limited availability, we have to use the shared patient rooms. Staff S52 further stated, Infection Prevention Program adhered to CDC (Centers for Disease Control and Prevention) guidelines.</p> <p>In an interview on 9/23/19, at 1:34 p.m., Staff S52 reviewed the medical chart history and confirmed that Patient #69 was never on a Foley catheter while in inpatient status starting from 9/16/19. She further confirmed Patient #70 (who is not on contact precaution) still shared the room with Patient #69. When asked about Patient #69's hand hygiene that "Needs Reinforcement" on 9/19/19 and 9/20/19, Staff #S52 stated that would be a reason to keep Patient #69 on contact isolation.</p> <p>Review of Progress Note, by Staff S700, on 9/18/19 reflected "Patient (#69) is positive for Klebsiella Pneumonia ESBL in the urine 9/15/2019 ... has long as patient urine is contained and patient ... can perform hand hygiene on their own. Patient does not need to be isolated."</p> <p>Review of CDC's Guideline for Isolation</p>	A 749			

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A 749	<p>Continued From page 293</p> <p>Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007, (<a href="https://www.cdc.gov/anthrax/pdf/infection-control-guidelines-for-healthcare-setting-2007.pdf">https://www.cdc.gov/anthrax/pdf/infection-control-guidelines-for-healthcare-setting-2007.pdf</a>), page 104 and 132, accessed 9/26/19, reflected "Multidrug-resistant organisms (MDROs), infection or colonization (e.g., MRSA ... ESBLs ...)." Precautions included " ... Contact Precautions recommended in settings with evidence of ongoing transmission, acute care settings with increased risk for transmission ..." Additionally, "Epidemiologically important pathogens. Infectious agents that have one or more of the following characteristics: 1) are readily transmissible; 2) have a proclivity toward causing outbreaks; 3) may be associated with a severe outcome; or 4) are difficult to treat. Examples include ... Klebsiella ..."</p> <p>Review of 2019 Infection Prevention Risk Assessment reflected "Probability the Risk will occur" was given a score of 3 (High) from a scale of 0 to 3 under the "Event" category of MDROs.</p> <p>Review of Standard and Transmission Based Precautions, policy #3000, with last revision date of 09/11/2018, reflected the purpose was "to prevent the transmission of healthcare associated or community acquired organisms and/or infections to our patients, visitors, and Workforce members."</p> <p>Review of Infection Prevention &amp; Control Program (dated September 2019), reflected "Infection Prevention Program Plan includes ... prevention, control, investigation of diseases ..."</p>	A 749			

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A 749	Continued From page 294  2) Review of Staff #S431's Tuberculin Skin Test (TST) Reading Record reflected he received an "Exposure Baseline TST" with a "Negative" result on 10/25/18. The date of next TST reflected 11/30/18 with no evidence of follow up test results as of 9/25/19.  In an interview on 9/25/19, at 2:05 p.m., Staff S52 stated "Exposure Baseline TST" is done when staff is identified as having occupational exposure to TB source. Staff S52 stated the date of next TST reflected as 11/30/18 was incorrect and the correct date should have been the next routine exam date of 2/4/19.  In an interview on 9/25/19, at 2:35 p.m., Staff S274 stated, Staff S431 should have received a follow up TST test 8-10 weeks (based on CDC guidelines) after the initial negative TST result (10/25/18). Staff S274 confirmed Staff S431 had not received TST testing since 11/30/18. Staff S274 stated when this test is overdue, an email is sent to the employee and the employee's "leadership." Staff S274 further stated Staff# S431 has been non-compliant but there was no evidence of any disciplinary action.  In an interview on 9/26/19, at 10:51 a.m., Staff S100 stated, when employee is delinquent on screenings (such as TST screening), email notification is sent to the employee's manager. Staff S100 stated there is no communication with Infection Prevention team regarding this matter unless test results come out positive.  In an interview on 9/26/19, at 11:48 a.m., Staff#S701 and staff #S56 stated, Staff #S431	A 749			

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A 749	<p>Continued From page 295</p> <p>continued working at the hospital but was suspended as of 9/25/19 after being notified of TB testing non-compliance by Staff#S274.</p> <p>Review of CDC's Guidelines for the Investigation of Contacts of Persons With Infectious Tuberculosis, reference # 54(RR15);1-37, (<a href="https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm">https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm</a>), accessed 9/26/19, reflected "Diagnostic and public health evaluation of contacts. This section discusses diagnostic evaluation ... The recommended period between most recent exposure and final tuberculin skin testing has been revised; it is 8-10 weeks ..."</p> <p>Review of Tuberculosis Prevention &amp; Control Plan 2019, approved by Infection Prevention Committee on 2/15/19 reflected the following under responsibilities:</p> <p>- "C. Departmental Leadership shall: ...3. Monitor compliance of employees with exposure follow-up and annual TB screening; document non-compliance, counsel, re-educate and apply progressive discipline to non-compliant employees ..."</p> <p>Review of policy titled Tuberculosis Screening, policy #:3.55.10, with effective date of 03/16, reflected the following: Policy Statement:</p> <p>- "... Tuberculosis (TB) screening program shall be used to ... 2. Identify TB infection in employees ... to prevent progression to TB ... 3. Evaluate the effectiveness of TB exposure control measures in</p>	A 749			



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A 749	Continued From page 296 order to identify the need for corrective action ..."  General Provisions: - "A ... Failure to comply is subject to disciplinary action (see Harris Health Policy 6.20 Employee Discipline)."  - "I.7. If there has been a determination of ongoing transmission periodic screening will occur at a period of every eight to ten (8 to 10) weeks ..."  - "J. Post Exposure Screening ... 2. Employees ... will be notified by EHS that they must participate in post-exposure follow-up and that they have one week to complete either post-exposure baseline testing or post-exposure follow up testing."  - "K.3. Employees ... with negative results by TST ... will be followed on routine scheduled basis."  Review of policy titled Corrective Action, policy #6.20, with last review date of 08/30/2019, reflected the following under Corrective Action System:  - "A.1. Supervisors may take Corrective Action against employees based on loss of confidence or the employee's lack of sound judgement in connection with the employee's Job Performance, Misconduct, or conduct witch otherwise interferes with the safe and efficient operation of Harris Health."  - "A.4. Corrective Action may include ... counseling, probation, corrective suspension, demotion, termination."	A 749			

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A 749	Continued From page 297  3) During a tour of the 5th floor units (5G and 5F) in Hospital #1 on 9/16/19, at 10:25 a.m., with Staff #S62 and #S64, the following observations were made:  - 5G Nourishment Room: cabinet below coffee machine storing disposable cups/lids were dirty with stains.  - 5G Medication Room: cabinet under the sink was locked with plastic securing device. Upon opening the cabinet, thick layer of dust was found inside. Additionally, there was a rusty metal object that was stuck in the sink drain.  - 5G Clean Supply Room and 5F Biohazard/Dirty Room: cabinet under sink was locked with plastic securing device. A thick layer of dust and stains were found inside the cabinet.  - 5F Nourishment Room: water dispenser had various rust spots. The surveyor also took a paper towel and wipe against the rust spots and found additional sticky substance. This was also verified with Staff S62.  In an interview on 9/16/19, at 10:40 a.m., Staff S62 and S64 confirmed the above findings. Staff#S64 stated he previously submitted a maintenance request to come and look at the sink in 5G Medication Room.  In an interview on 9/16/19, at 11:30 a.m., in the 5G Clean Supply Room, Staff #S64 stated, "while back, the floor Director decided to place a seal (plastic securing device) to the cabinets because	A 749			

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A 749	<p>Continued From page 298</p> <p>they decided not to use them. So EVS (Environmental Services) have not been cleaning them ever since the seals were placed, but they should be cleaned."</p> <p>Review of Request Work Order (WO# 1421332) dated 9/16/19, at 11:02, reflected "Water not drain properly metal string is block in next to the pharmacy pyxis sink on 5G ..." Work order status reflected "completed" by Staff S606 on 9/17/19 at 8:59 a.m.</p> <p>During a tour of 1st floor in Hospital #1 on 9/19/19, at 11:05 a.m., with Staff S52 and S605, the following observations were made:</p> <ul style="list-style-type: none"> <li>- Satellite Accumulation Room (storing various biohazard waste): various stains on walls, dirty floors with dust and debris, multiple base racks/pallets that stored various waste items had thick dust and debris accumulation and numerous spider webs in the openings on those racks/pallets.</li> </ul> <p>In an interview on 9/19/19, at 11:05 a.m., Staff #S605 confirmed the above findings and stated EVS was supposed to clean the area on daily basis. Staff #S605 confirmed the area did not appear to be cleaned on daily basis.</p> <p>During a tour Oxidizing Gas Storage Room on 9/20/19 at 11:00 a.m., 1 of 2 bed had dust accumulation, piece of straw covering, and alcohol wipe on the bed frame below the mattress.</p>	A 749			

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A 749	<p>Continued From page 299</p> <p>In an interview on 9/20/19, at 11:00 a.m., Staff #S119 stated "these beds are supposed to clean beds." She then had the bed taken out of the room to be cleaned.</p> <p>During a tour of Room 5B1 (unoccupied room ready for new patient) on 9/20/19, at 2:35 p.m., patient bed had a dried, dark red colored stain to the bedframe.</p> <p>In an interview on 9/20/19, at 2:35 p.m., Staff #S124 confirmed the above finding.</p> <p>Review of policy titled Environmental Services Cleaning Guidelines, policy # 7200, with effective date of 05/17, reflected " ... To ensure standardized cleaning protocols that enhance our patient experience by providing a high level service to produces a clean, safe and healthy environment ... EVS contributes to the quality, safety, and aesthetics of our environment by providing regularly scheduled cleaning of most non-critical environment surfaces under the guidance of our Infection Prevention policies." Cleaning responsibilities under "Tasks" reflected the following:</p> <ul style="list-style-type: none"> <li>- EVS: included floor care maintenance, ice machine cleaning, supply room, supply room (dirty)</li> <li>- Unit: medical equipment, stretcher cleaning</li> </ul> <p>The above policy did not specify any cleaning requirements for Nourishment Room, Medication Room, nor Satellite Accumulation Room. The</p>	A 749			

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A 749	<p>Continued From page 300</p> <p>"Task" items/areas did not have any further details on cleaning procedures for each "Task."</p> <p>Review of Infection Prevention &amp; Control Program (dated September 2019), reflected "Infection Prevention Program Plan includes ... Maintenance of a sanitary physical environment ... cleaning and disinfecting surfaces, carpeting, and furniture ... disposal of regulated and non-regulated waste ..."</p> <p>Findings:</p> <p>On 9-25-2019 at 10:00 AM, a review of employee files was made at Hospital #2 with Staff #S329 and Staff #S330. During the review of TST documentation, it was noted that the record provided did not include the time the test was administered to staff or the time the test was read by the employee health nurse. Further documentation was requested from the employee health nurse to determine if there was additional documentation in the employee health office that included this information. Follow-up information provided by Staff #S329 and Staff #S330 confirmed that this information was not documented.</p> <p>Review of the CDC website, <a href="https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm">https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm</a> was as follows:</p> <p>"How is the TST Read? The skin test reaction should be read between 48 and 72 hours after administration. A patient who does not return within 72 hours will need to be rescheduled for another skin test.</p>	A 749			

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A 749	<p>Continued From page 301</p> <p>The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis)."</p> <p>Since the accuracy of the test depended on the results being evaluated within the 48 to 72-hour window from administration to reading, and the required times of administration and reading of results was not documented, the results of the TST for all employees who had been tested could not be verified as accurate and/or correct.</p> <p>Findings:</p> <p>Observation on 9/16/19 at 10:00 am of Hospital 2's loading dock area showed, there was a cart full of clean sharps containers made to be placed in patients' rooms. Directly adjacent to this was a cart full of dirty linen. Although the dirty linen was loosely covered with a thin plastic sheet, it was still in contact with the clean cart carrying the clean sharps containers.</p> <p>Record review of facility policy titled "Management of Hazardous Materials", policy No. 7201, Appendix A, stated" ....medical waste will be kept separate from ordinary trash and segregated ....".</p> <p>In an interview on 9/16/19 at 10:00 with Safety Specialist Staff #S374, he stated, the cart carrying the clean sharps containers should not have been next to the dirty linen cart but rather,</p>	A 749			

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A 749	<p>Continued From page 302</p> <p>should have been located on the 'clean' side of the doors leading into the warehouse. Staff #S374 stated that one side of the loading dock to the warehouse was considered dirty and the other side was considered clean. The clean cart with the sharps containers was located on the dirty side.</p> <p>Observation on 9/16/19 at 10:15 AM of the primary warehouse and storage area of Hospital 2 showed, there were 15 clean beds covered with this plastic sheets. In the same area, intermingled with the clean beds, were also 18 dirty beds that needed repairs, covered in a thin blue plastic covering.</p> <p>In an interview on 9/16/19 at 10:15 with Staff #S378, he stated that keeping the clean beds and the other [dirty] beds in the same area, some of which were in contact with each other, was the usual practice of Hospital 2. When it was explained to him that this was an infection control issue due to the possibility of cross contamination, he stated, he understood and proceeded to have the clean and dirty beds separated and stated that before the clean beds went back to a patient's room, they would also be cleaned and sanitized first.</p> <p>Observation on 9/16/19 at 11:00 AM, of "Crash Cart Supply Room" on the first floor of Hospital 2 revealed, there were patient-use items stored in two boxes on the floor, not on a palette or shelf, allowing possible contamination from use of a cleaning mop. There was one box approximately 2' x 2' x 2' that was full with over 20 "Comfortgel"</p>	A 749			

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A 749	<p>Continued From page 303</p> <p>pads for patient pain relief (non-pharmaceutical) and one large box of the patient IV solution - Dextrose 5%, 500 cc's per bag. There were at least 20 bags in the box, which measured approximately 2' x 2' x 2'.</p> <p>In an interview on 9/16/19 at 11:00 AM with Staff #S222, he stated that he knew it was wrong to store any patient supplies directly on the floor and removed the possibly contaminated boxes.</p> <p>Observation on 9/17/19 at 1:30 PM, at Hospital 2's Obstetrics department's clean supply room showed, there was no splash guard on the bottom shelf of a metal framed cart which contained patient use supplies. The shelves were composed of thin metal bars open to the bottom. Housekeepers who mopped the inside of the room had the potential to 'splash' contaminated water/cleaning solution onto the patient use supplies.</p> <p>In an interview on 9/17/19 at 1:30 PM with Staff #S181, she stated, she understood the potential for contamination and removed all supplies from the shelf.</p> <p>Observation on 9/19/19 at 11:15 AM, at Hospital 2's third floor (3D) MICU (Medical Intensive Care Unit) showed that occupied Room #9 had a dried dark rust-colored spot resembling blood on the floor, next to bedside. It measured approximately 1.5 inches in diameter and had several droplets of splattered dried liquid surrounding the spot. In an interview on 9/19/19 at 11:15 AM, Staff #S380</p>	A 749		



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A 749	<p>Continued From page 304</p> <p>stated, the spot on the floor appeared to be blood, then promptly cleaned the area using disinfectant wipes.</p> <p>Findings:</p> <p>1) During a Hospital 1 Unit tour on 09/18/19 at 1120, Staff #S291 identified items in Room 4.219 as clean equipment. The items included a wheel-chair and a three-shelf portable metal cart.</p> <p>The wheel-chair's rubber wheels and metal spokes were dusty and grimy. Per surveyor request, Staff #S290 wiped the spokes down with a paper towel; it was dark discolored.</p> <p>The three-shelf metal cart was dusty. Staff #S290 wiped it down, and the paper towel returned dark colored. The employee acknowledged the above findings at that time.</p> <p>During an interview on 09/18/19 at 1120, Staff #S290 stated she surveyed the unit quarterly.</p> <p>2) A unit tour on 09/20/19 at 1355 reflected an occupational therapy room used by patients had a dusty storage shelf. The floor and the wall under the sink were discolored and stained. Staff #S3 acknowledged the findings at that time.</p> <p>3) Observations in the bathroom of Room #4.222 (Patient Room #5) on 09/20/19 at 1440, reflected scum around the sink water faucet and toilet. Staff #S294 took a paper towel at that time and wiped around the water faucet. The paper towel came back dark discolored.</p>	A 749			

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A 749	Continued From page 305  Observations on 09/20/19 between 1445 and 1450 reflected the following:  The bathroom of Room #4.220 (Patient Room #4) had a sink with scum and grimy discoloration and a yellow-stained toilet.  A dirty toilet, scum around the sink, and a lack of toilet paper and paper towels were noted in the bathroom of Room #4.214 (Patient Room #1).  Patient Room 4.216 (Patient Room #2) had a sink with grimy discoloration under the faucet in the bathroom.  The bathroom of Room 4.218 (Patient Room #3) had a faucet with grimy discoloration.  Staff #S294 and Staff #S3 acknowledged the above findings at that time.  Record review of the Infection Prevention Plan 2019 reflected the Infection Committee's responsibility to recommend "infection prevention and control measures needed to protect patients ...and employees ..."  Hospital # 2 :  Record review of facility policy titled "Hand Hygiene Guidelines," dated 08/26/19, showed that staff are to perform hand hygiene before and after patient contact, after contact with a source of microorganisms, and after wound dressing. Hand hygiene should be performed between glove changes.	A 749			

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A 749	Continued From page 306  Review of facility policy titled "Personal Protective Equipment," dated 06/12/18, showed that exam gloves are to be worn for all direct contact during a non-sterile procedure. Gloves should be removed immediately without touching non-contaminated surfaces when the patient care task is completed.  a. Patient # 405:  Record review of the clinical record of Patient #405 showed a physician order, dated 9-24-19 that read: wash all wounds, apply isosorb to all open wounds, can pack puracol to right thigh wound , sensicare to intact skin around sacrum; change dressing every day or if dressing is soiled or loose.  Observation on 09-24-19 at 10:30 A.M., showed staff # S704 performed wound care on Patient # 405. Staff S704 was assisted by staff #S703.  Staff #704 gathered the wound care supplies. Staff S703 entered the room, she failed to sanitize her hands prior to donning exam gloves.  Both staff rolled Patient #405 to his left side. Both staff cleaned a large amount of feces prior to proceeding with wound care.  Staff #S703 failed to change gloves immediately after cleansing the patient. While wearing contaminated gloves, she placed the aloe cleaning spray into the bedside table. She proceeded to a large bag of supplies located on a sofa in a room. Staff S703 looked thorough the bag of supplies, still wearing the contaminated	A 749			

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A 749	<p>Continued From page 307 gloves.</p> <p>Staff #S704, while wearing the same gloves used to clean feces, removed the old dressing from Patient # 405's right thigh. Patient # 405 had a large (approximately 4 inch x 6 inch) open, Stage III pressure ulcer to his upper right thigh. Staff S704 then changed gloves and sanitized her hands.</p> <p>Staff #S704 failed to sanitize her hands three (3) times between gloves changes during the procedure.</p> <p>Staff #S703 failed to change gloves appropriately and sanitize her hands during the procedure.</p> <p>During an interview on 09-25-19 at 10 A.M., with Staff S495 she stated, staff needed to sanitize their hands between glove changes.</p> <p>b. Patient #403:</p> <p>Observation on 09-24-19 at 8:15 A.M., showed Staff S702 prepared to administer medication to Patient # 403.</p> <p>During the medication administration process, Staff #S702 changed her gloves twice and failed to sanitize her hands between the glove changes.</p> <p>After Staff S702 finished giving the medication, she exited the room with the workstation on wheels (WOW) that contained the medication. Staff #S702 failed to sanitize the WOW after exiting the room; she wheeled into the medication supply areas.</p>	A 749			

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A 749	<p>Continued From page 308</p> <p>During an interview on 09-24-19 at 10 A.M. with Staff #S728 she stated, the WOWs should be wiped down with the disinfectant wipes after exiting the patient's room.</p> <p>Findings:</p> <p>During observation of a percutaneous nephrostomy tube placement in Hospital #1 interventional radiology on 9/17/19 at approximately 10:00 am, Staff #S110 was observed, while setting up the sterile supplies, grasp the garbage receptacle to pull it closer and then proceeded to continue to open sterile supplies without first washing his hands or using hand sanitizer after touching the garbage receptacle.</p> <p>In interviews with staff #S110 during the procedure on 9/17/19 at approximately 10:35 am, staff #S110 acknowledged these findings.</p> <p>In an interview with MRT supervisor, staff #S111 on 9/17/19 at approximately 11:30 am, the above finding was acknowledged.</p> <p>Findings:</p> <p>On 09/16/2019 at 9:49 a.m., during tour of the facility's hemodialysis unit located on the 6th floor of Hospital 1, revealed eleven hemodialysis stations with cloth curtains separating each station. Observation revealed 6 stations were observed being utilized for hemodialysis treatment of patients.</p> <p>Observation on 09/16/2019 at 10:25 a.m. of station #2 revealed Staff #S41 was observed</p>	A 749			

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A 749	<p>Continued From page 309</p> <p>terminating hemodialysis treatment on Patient (#13). During the termination process, the Staff #S41 removed the contaminated blood line and dialyzer and discarded them in the red contaminated biohazard container which was in direct contact with the hanging curtain shared by another patient in the adjacent station. The hanging curtain came in direct contact with the contaminated blood line and dialyzer during the process of discarding them in the red biohazard bin.</p> <p>On 9/16/2019 11:21 a.m., Staff #S42 was observed terminally cleaning the station #2 in preparation for an on-coming Patient. The contaminated curtain remained in place.</p> <p>Observation on 09/16/2019 at 11:30 a.m., of station #3 revealed Staff #S42 was observed terminally cleaning hemodialysis station 3 which was utilized by Patient (#15) for hemodialysis treatment.</p> <p>Observation revealed the Staff #S42 discarded the contaminated hemodialysis external blood line and dialyzer into the red biohazard bin with was located in direct contact with the hanging curtain shared with station #4. Staff #S42 also touched the curtain with his contaminated gloves.</p> <p>Observation on 09/16/2019 at 11:50 a.m., revealed Staff #S42 was observed terminally cleaning the unit. The contaminated curtain remained in place.</p> <p>Interview on 09/16/2019 at 11:58 a.m., with the Hemodialysis Unit Director revealed there was no set schedule for cleaning of the curtains. Sometimes they are cleaned every three months</p>	A 749			

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A 749	<p>Continued From page 310 or when necessary.</p> <p><b>TERMINAL CLEANING OF HEMODIALYSIS MACHINE</b></p> <p>On 09/16/2019 at 11:10 a.m., Staff #S47 was observed on the hemodialysis unit at hospital #1, at station # 4. During terminal cleaning of the hemodialysis machine which was used to hemodialyzed Patient (#14), The Hansen Connectors were not cleaned or disinfected.</p> <p>On 09/16/2019 at 11:21 a.m., revealed Staff #S42 was observed on the hemodialysis unit of Hospital #1. The Staff #S42 was observed terminally cleaning and disinfecting hemodialysis machine 5169 which was utilized by Patient #13 for hemodialysis treatment. Observation revealed during terminally cleaning of the unit the Staff #S42 did not clean and disinfect the wands, Hansen connectors and back of the machine while terminally cleaning the unit.</p> <p>Review of the Manufacture's recommendation 2008T Manufacture's operating manual, P/N 490122 REV U Page 180 directs users as follows:</p> <p>After every treatment the exterior surface of the machine should be wiped down using a cloth and a disinfecting cleaner.</p> <p>During an interview on 09/16/2019 at 11:45 a.m., with the hemodialysis Unit Manager, and Staff #S43 and #S47 revealed, the surveyor notified them that the Hanson connectors, wands, and back of the dialysis machines were not cleaned</p>	A 749			

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A 749	<p>Continued From page 311 and disinfected during terminal cleaning of the unit.</p> <p>The Unit Manager instructed Staff #S43 to re-clean the hemodialysis machines.</p> <p>Central Venous Catheter Care</p> <p>Patient #16</p> <p>On 09/16/2019 at 11:04 a.m., Registered Nurse #S43 was observed terminating hemodialysis treatment on the Patient #16 who had a central venous catheter in place used for hemodialysis treatment. Observation revealed during disconnection of the external blood line from the central venous catheter, the Patient was not wearing a mask to prevent contamination of the central venous catheter. The surveyor notified the Registered Nurse of her observation. Registered Nurse #S43 stated "OK"</p> <p>Subsequent observation revealed Registered Nurse #S43 applied a mask to the Patient's face. During the process, he touched the patient's ear and face with his gloved hands. Registered Nurse #S43 then flushed and packed the Patient's central venous catheter using his contaminated gloved hands.</p> <p>On 09/16/2019 at 11:25 a.m., the surveyor notified the Registered Nurse of break in infection control while providing central venous catheter care to the Patient. Staff #S43 stated, " You are correct."</p> <p>Patient #15</p>	A 749			



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A 749	Continued From page 312  On 09/16/2019 at 11:30 a.m., observation of Patient (#15) revealed, Registered Nurse #S41 was observed terminating hemodialysis treatment on the Patient who had a central venous catheter in place used for hemodialysis treatment. Observation revealed, the Registered Nurse was observed terminating hemodialysis treatment on Patient (#15) left double lumen central venous catheter used for hemodialysis treatment.  Observation revealed, registered Staff #S41 applied a mask to his face, picked up a pair of gloves from the clean box of gloves and donned it, then applied a mask to the Patient's face. Staff S#41 gloved hands came in direct contact with the patient's ear and head and also touched the side rails with his gloved hands. Staff S#41 then disconnected the external blood line from the Patient's central venous catheter and packed the Patient's central venous catheter. Staff S#41 did not wash/ sanitize his contaminated hands and changed gloves after masking himself and the Patient.  On 09/16/2019 at 11:41 a.m., the Surveyor notified Staff #S41 of her observation of using his contaminated hands to disconnect, flush and pack the Patient's central venous catheter. Registered Nurse #S41 stated, "I am sorry"  On 09/16/2019 and 09/18/2019, the Surveyor requested copies of policy and procedure for care of central venous catheter from the hemodialysis unit manager and hostess. None was provided.  Review of the facility's current policy on	A 749			

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A 749	<p>Continued From page 313</p> <p>Hemodialysis Infection Prevention and Control Policy # 2302 effective 02/1978 and revised on 09/23/2019 after the Surveyor requested the policy, revealed the following directive:</p> <p>" The dialysis station (e.g., chairs, beds, tables, machines televisions clamps blood pressure cuffs) must be cleaned and disinfected with 1:100 bleach solution, between patients unless otherwise specified by manufacturer recommended product that is system approved."</p> <p>" Dialysis machines shall be disinfected with bleach solution (1:100) and shall be performed as scheduled within the unit or---- by nursing staff wearing PPE."</p> <p>Hospital #1</p> <p>Findings:</p> <p>The hospital did not follow the manufacturer's directions regarding probe covers (sterile sheaths) for endocavity transducers used in the obstetrics clinic.</p> <p>On the afternoon of 9/18/2019, a tour of Hospital 1 Obstetrics clinic located on the fourth floor of the tower building was conducted. During observation in the obstetrics clinic cleaning room it was noted that endocavity transducers were hanging in a storage cabinet. Closer examination revealed that there were approximately 12 endocavity transducers and each was covered with a blue disposable glove. The gloves had handwritten dates on them indicating when the transducer had been disinfected. The blue gloves were observed to be loose fitting and thus allowing air to enter the glove.</p>	A 749			

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A 749	Continued From page 314  Review of the General Electric Voluson E8 Basic User Manual 48701RU Revision 3 (provided to the survey team for review) revealed that Chapter 5 provided information about probes and biopsies. Page 5-2 of chapter 5 stated in the "Caution" section: "In addition to cleaning and disinfection the use of sterile, legally marketed probe sheaths for intracavity procedures is mandatory."  Continued review of the General Electric Voluson E8 Basic User Manual 48701RU Revision 3, revealed on page 5-12 of chapter 5: "Covering the Transducer using a Sterile, Protective Sheath" that:"2. Insert transducer into sheath, making sure to use proper sterile technique. Pull cover tightly over transducer face to remove wrinkles and air bubbles, taking care to avoid puncturing the sheath."  Figure 5-11 provided an illustration of applying the sheath. Under the illustration of how to apply the sheath were the comments: "1. Secure the Sheath with a rubber band. 2. The probe sheath should extend past the end of the probe over the probe's cable. 3. Secure the sheath in place." Also found was the comment: "Note Failure to use a sheath that fully covers the transducer to the cable stain relief area may lead to cross-contamination of the transducer. 4. Inspect the sheath to ensure that there are no holes or tears."  Review of "Probe Sterilization Procedure" document found in the obstetrics clinic cleaning room stated: "6. Dry Probe And Apply Cover." "8	A 749			

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A 749	<p>Continued From page 315 .... Ultrasound probe should be covered with sheaths after sterilization..."</p> <p>When the survey team asked staff #S324 what type of sheath was used on the probe during patient procedures, the surveyors were shown a box labeled "Sheathing Sheathes Technologies." The labeling indicated that the box was item number #10001 and stated, "100 Latex Rolled Ultrasound Probe Covers." Also found on the label was, "Non-Sterile." The label stated: "Follow manufacturer's instructions for cleaning and disinfecting the transducer." The side panel label indicated that probe covers that were available included sterile kits, sterile individually wrapped as well as non-sterile. The other side panel of the box listed that probe covers were available as non-sterile bulk, sterile individually wrapped as well as non-sterile individually wrapped. Also listed in bold lettering was: "Sterile Ultrasound Probe Cover Kits."</p> <p>A review of the facility's policy titled, "Pre-Cleaning, Sterilization, High and Low-level disinfection, and Storage of the processed patient care devices" revealed the following:</p> <p>"APPENDIX M</p> <p>STORAGE AND TRANSPORTATION OF PATIENT CARE MEDICAL DEVICES AND OTHER PATIENT CARE ITEMS AFTER STERILIZATION OR HIGHLEVEL DISINFECTION</p> <p>A. Scopes should be hung upright in a covered cabinet for storage after processing.</p>	A 749			

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A 749	<p>Continued From page 316</p> <p>B. If scopes are transported to another area for storage, they may be transported in a rigid container."</p> <p>Store the device in a manner that will protect from damage or contamination and that is consistent with national guidelines and manufacturers' recommendations such as hanging vertically in a cabinet and storing in a clean environment. The use of gloves can cause moisture and the results of bacteria growth.</p> <p>In an interview with staff member #S324 on the afternoon of 9/18/2019 it was confirmed that non-sterile sheaths were used during patient procedures. In a follow up interview with staff member #S324 on the morning of 9/19/2019, the survey team was told that the OB clinic had been in its present location in the tower building for three years and that blue gloves had been used for storing the probes during that time.</p> <p>Sharps containers.</p> <p>Observation of the Hospital 2 warehouse on 9/25/2019 at 10:15 AM, showed a cage located 40-50 feet from a loading dock door. The cage housed sharps containers, some with lids, others without. Three (3) stacks of large sharps containers had been placed on the floor. There was a light layering of dust on the sharps containers located just to the right of cage door. At the back right side of the cage were sharps containers with a thick layer of dust and dirt. These sharps containers did not have lids. There were corrugated boxes stacked in front of the back wall of the cage. Due to the misalignment of the stacked corrugated boxes, the integrity of</p>	A 749			

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A 749	<p>Continued From page 317</p> <p>the boxes was compromised as evidenced by buckling of the sides and corners of the boxes. Not all of the outer flaps were in the closed position. The contents were dusty.</p> <p>In an interview with Staff S227 in the Hospital 2 warehouse on 9/25/2019 at 10:15 AM, he stated the, sharps containers at the front of the cage had been delivered "about an hour ago" and will be "processed" by the end of the day. He also stated the sharps containers without lids toward the back of the cage had been in the cage more than a day. He concluded by saying, the three (3) stacks of large sharps containers that had been placed on the floor should have been placed on pallets.</p> <p>In an interview with Staff S470 at Hospital 2 on 9/25/2019 at 10:20 AM, he stated, the sharps containers in the cage were "clean," adding, "Everything in the cage is clean." He also stated, the sharps containers are removed from the cage by a technician and delivered to the units. He concluded by stating that he did not think the technician cleaned the sharps containers prior to delivering them to the hospital units.</p> <p>In an interview with Staff #S471 at hospital 2 on 9/25/2019 at 10:30 AM, he stated, everything in the cage was not clean, deliveries to the unit were made Monday, Wednesday, and Friday, and he delivered the sharps containers to the unit without cleaning them. He identified the contents in the corrugated boxes as being brackets and covers for the sharps containers. He concluded by saying that the process of storing the sharps containers "needs to be changed."</p>	A 749			

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A 749	<p>Continued From page 318 Dialysis Solutions.</p> <p>Observation of the Hospital 2 warehouse on 9/25/2019 at 10:10 AM, showed six (6) one-gallon containers of Minncare Cold Sterilant used in dialysis, not in their original shipping boxes. The containers had a layer of dust on them. Further observation showed 16 one-gallon containers of Renal Pure. They, too, were covered with a layer of dust. Two of the containers of Renal Pure had fallen on their side.</p> <p>In an interview with Staff #S227 in the Hospital 2 warehouse on 9/25/2019 at 10:10 AM, he stated that the containers of Minncare Cold Sterilant and Renal Pure should have been in boxes or covered. He further stated that a technician had taken the Renal Pure out of corrugated boxes, then realized that he had unpacked the wrong solution. The technician did not repack them. He concluded by saying the dialysis solutions are delivered to the dialysis area from the warehouse and are not wiped down prior to delivery.</p> <p>Hospital (2)</p> <p>Observations during the tour at Hospital 2, of the dialysis treatment room with 8 stations on 9/16/2019 at 10:30 am revealed the following:</p> <p>Contact Isolation room #8 lights off, patient dialyzing unable to view patient access, attending nurse did not have Personal Protective Equipment (PPE) impervious gown tied.</p> <p>Dialysis station #1 had clean supplies stored on the Marcor portable reverse osmosis (RO) machine # 60002634. Dialysis Machine #60004835 had a staff cell phone on top.</p>	A 749			

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A 749	<p>Continued From page 319</p> <p>Tour of the dialysis facility on 9/17/19 at 11:45 a.m., fabric privacy screen touching the dialysis machine at station #5, touching the trash between station #3 and # 4.</p> <p>Observation of Staff S#194 transporting a half-filled urinal to discard with gloves only.</p> <p>During interview with Staff S#195 and S#192 during the observation, the surveyor asked what was the process for disinfection after a Hepatitis B+ patient dialyses? Staff #S192 and #S195 stated that they have the room terminally cleaned.</p> <p>The Surveyor requested the date of the last known Hepatitis B+ patient to be dialyzed. August 12, 2019 was the date given, and review of the quarterly curtain change schedule revealed the Hemodialysis curtains had not been changed since 6/20/19.</p> <p>Observed Staff #S199 place an acid jug (from the storage room) on top of the dedicated clean supply cart where Staff S#193 was preparing a catheter pack.</p> <p>Observation at 12:30 P. M, a phoenix meter on the counter top at the nurses' station.</p> <p>Interview with Staff #S199 at that time stated "it is clean ".</p> <p>Surveyor asked Staff #S199 about the process for obtaining conductivity. Staff #S199 proceeded to walk to the dialysis machine and show how she obtains a sample from the port on the Hanson line, then takes the meter to the next machine to obtain conductivity.</p>	A 749			



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A 749	Continued From page 320  Surveyor noted there was no Reverse osmosis water or bleach water prepared and available to rinse and wipe the meter between obtaining samples.  Interview with Staff #S199 confirmed, she did not rinse the or disinfect the meter between uses. Interview with Staff #S192 stated, the proper procedure was to rinse the meter with RO water and disinfect the meter between uses.  Review of the Directions for Use "Taking Measurements" #4" Rinse the cell, syringe interior, and sampling cup/tube thoroughly with RO water after each use.  Observation on 9/17/19 at 11:58, revealed a "sitter" Staff S#197 pulling the privacy screen closed with dirty gloves then advised by staff S#195 to keep the screens open to allow for observation of Blood Pressure (BP) monitoring due to the monitor alarming. Staff S#193 requested Staff S#197 to retake the BP.  Staff S#197 asked "what button do I push on the monitor?". BP was obtained using the same gloves that touched the patient, the screens and the monitor and back to the patient to remove the blankets from the patients hemodialysis  Review of Staff #S197 personnel filed showed no evidence of hemodialysis training.	A 749			
A 940	SURGICAL SERVICES CFR(s): 482.51	A 940			

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A 940	<p>Continued From page 321</p> <p>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to:</p> <p>A. ensure the Transesophageal Echocardiogram Endoscope (TEE) and the transvaginal probes were stored in a manner that would protect them from damage or contamination and that was consistent with national guidelines and manufacturers' recommendations such as hanging vertically in a cabinet and storing in a clean environment. Also, that the facility followed their own policy on "Pre-Cleaning, Sterilization, High and Low-level disinfection, and Storage of the processed patient care devices. Further review revealed, the facility failed to monitor the temperature and humidity of the storage room where TEE probes were stored.</p> <p>It was determined that these deficient practices posed an Immediate Jeopardy to patient health and safety and placed all patients having a transesophageal echo, vaginal ultrasound, surgical procedure, and Cardiac Cath Lab procedure in the facility at risk for the likelihood of harm, serious injury, and possibly subsequently death.</p> <p>B. ensure the temperature in the Operating room (OR) was within acceptable standards to inhibit</p>	A 940			

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A 940	<p>Continued From page 322</p> <p>microbial growth, reduce the risk of infection, promote patient comfort, and assure the physical safety of all patients. The temperature and Humidity was out of range for 33 of 33 days reviewed from August 18, 2019, to September 19, 2019. There was no documentation on the log after a follow up that indicated corrective action had been taken regarding the out of range temperatures. The operating room staff was not knowledgeable of the temperature requirements prior to opening sterile cases in the Operating Room. The was no continuous monitoring of temperature and humidity in the Cath Lab #1, Cath Lab #2, and Cath lab storage room where sterile wrapped pacemaker trays were stored.</p> <p>It was determined that these deficient practices posed an Immediate Jeopardy to patient health and safety and placed all patients having a transesophageal echo, vaginal ultrasound, surgical procedure, and Cardiac Cath Lab procedure in the facility at risk for the likelihood of harm, serious injury, and possibly subsequently death.</p> <p>C. ensure documentation in the surgical chart that the time out was accurately completed and included all elements of a complete Time Out.</p> <p>D. ensure a sanitary environment for the provision of surgical services and patient care for 25 (Cath Lab #1, Cath Lab #2, Cath Lab Sterile Storage Room, Bronchoscopy scope processing room, bronchoscopy supply storage room, sterile processing clean preparation area, sterile processing autoclaves, sterile processing instrument storage room, Floor 3 - OR 14, OR 15,</p>	A 940			

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A 940	<p>Continued From page 323</p> <p>OR 6, Anesthesia supply room, Supply core next to charting area, Labor &amp; Delivery (L&amp;D) storage room, Probe storage room (OG-10), GI Lab #3, GI scope processing room, Main OR Floor 4 - OR 7, OR 11, Core area outside OR 3, anesthesia workroom, Core outside anesthesia workroom, sub-sterile room between OR 11&amp;12, Sterile Core area) of 25 areas observed.</p> <p>E. Based on observation, record review, and interview, the facility failed to ensure that the patient was provided all information necessary to make an informed decision on their care in 8 (Patient #'s 41, 42, 44, 203, 204, 206, 207, and 208) of 8 surgical charts reviewed.</p> <p>HOSPITAL #2</p> <p>Based on observation interview and record review, the facility failed to:</p> <p>A. ensure the temperature in the Operating room (OR) was within acceptable standards to inhibit microbial growth, reduce the risk of infection, promote patient comfort and assure the physical safety of all patients in 10 (OR's #1, #2, #3, #4, #5, #6, #11, #12, #13, and #14) of 11 areas observed. The temperature was out of range for 30 of 30 days reviewed. There was no documentation on the log to indicate corrective action taken or the temperature upon follow up after corrective action was completed. Further review revealed the facility failed to monitor the temperature and humidity of the storage room where the TEE probes were stored.</p>	A 940			

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A 940	<p>Continued From page 324</p> <p>B. maintain a clean and sanitary environment to ensure patients' health and safety in 9 (Post Anesthesia Care Unit, Cardiology Department, GI Lab, Sterile Core, Sterile Processing Department, Anesthesia Storage Room, Operating Suite 3rd floor, Pre-operative Holding area, and Storage Room 4th floor) of 9 areas observed.</p> <p>(C) . maintain a clean and sanitary environment to ensure patients' health and safety in in 9 (Post Anesthesia Care Unit, Cardiology Department, GI Lab, Sterile Core, Sterile Processing Department, Anesthesia Storage Room, Operating Suite 3rd floor, Pre-operative Holding area, and Storage Room 4th floor) of 9 areas observed.</p> <p>Hospital #2 failed to ensure a sanitary environment in that an ice machine was sitting on a cracked countertop such that the countertop could not be properly cleaned, instruments were found in peel pouches with tears, unwrapped oral airways were available for patient use, disposable scalpels were tucked between the layers of a wrapped crash cart kit, instruments were found in discolored peel pouches, hinged instruments in closed positions were packaged in peel pouches, instruments with unprotected tips were packaged in peel pouches that could breach the integrity such that sterility of the instruments could not be assured, chipped floor tiles were observed in front of steam sterilizers such that the floor could not be properly cleaned, a transesophageal echo probe (TEE) available for patient use was being stored horizontally in a hard plastic transparent transport case in a room where temperature and humidity were not monitored and not stored appropriately in a hanging or vertical position,</p>	A 940			

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A 940	<p>Continued From page 325</p> <p>paper sacks were used to store sterile supplies, paper sacks and staplers were stored next to sterile supplies, a medication Pyxis machine had dried dripping with debris, and re-usable bougies in peel pouches that had no reprocessing information regarding disinfection/sterilization were available for patient use.</p> <p>Findings:</p> <p>Hospital 1 B. TEMPERATURE AND HUMIDITY</p> <p>During a tour on September 18, 2019, after 1:00 p.m., the following observations were made:</p> <p>In OR #6, there was no temperature and humidity monitor in the room. Staff #382 was asked how the OR personnel monitored temperature and humidity prior to opening sterile cases and during surgical procedures. Staff #S382 stated, "Facilities Engineering department monitors those and will notify the OR if it is out of range." Staff #S382 was asked how the staff would know if Facilities Engineering department did not call. Staff #S382 stated, "We just monitor by feel. If it is too cold or hot or if there is condensation on surfaces, then we know." Staff #S382 was asked to call Facilities Engineering department and get a temperature and humidity for all the OR's on the third floor at that time.</p> <p>At 2:49 Staff # 386 called and reported the following readings:</p> <p>OG 7 - 64 degrees and 64.2% humidity OG 15 - 64.8 degrees and 55% humidity OG 14 - 63.4 degrees and 59% humidity</p>	A 940			

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A 940	Continued From page 326  The temperature was out of range in all three rooms reported. The humidity was out of range in one room reported. Staff #S124 and #S55 were asked if Facilities Engineering department had notified the OR of the levels that were out of range. Staff #S124 and #S55 confirmed they had not.  A request was made for Facilities Engineering department to come do a recheck on OR 7, as a sterile procedure was being done in that room and the humidity was out of range. At 3:03 p.m., Staff #S385 did a manual recheck of OG 7. The reading was 67.1 and 59%. Staff #S385 was asked why there was an almost 5% difference in the recheck of the humidity. Staff #S385 explained that temperature and humidity was not monitored in each individual room. Staff #S385 stated, "We do average temperature and humidity in the OR. For example, if there are two air handlers in one area that provide air-conditioning to the OR's then we would average the temperature and humidity readings from both.  Staff #S385 was asked if Facilities Engineering department continuously monitors the temperature and humidity for the OR's. Staff #S385 stated, "yes, we do". Staff #385 was asked why Facilities Engineering department had not made any notification to the OR's about the ranges out of range as reported earlier on the phone. Staff #S385 then stated, "Well we usually only call at the 5 a.m. check." Staff #S385 was asked to clarify that if the ranges for temperature and humidity were out of range outside of the 5	A 940			

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A 940	<p>Continued From page 327</p> <p>a.m. check that there was no notification to the OR. Staff #S385 stated, "Yes, mam, usually that's the case."</p> <p>Review of the facility temperature and humidity logs for August 18 to September 19, 2019 revealed the following:</p> <p>FLOOR 3</p> <p>OG 10 The temperature was documented out of range 11 of 33 days reviewed.</p> <p>OG 12 (OR 13) The temperature was documented out of range 3 of 33 days reviewed.</p> <p>OG 8 The temperature was documented out of range 9 of 33 days reviewed.</p> <p>OG 14 The temperature was documented out of range 18 of 33 days reviewed.</p> <p>OG 15 The temperature was documented out of range 8 of 33 days reviewed.</p> <p>OG 7 The temperature was documented out of range 33 of 33 days reviewed. The humidity was documented out of range 13 of 33 days reviewed.</p> <p>OG 6 The temperature was documented out of range</p>	A 940			



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A 940	Continued From page 328 33 of 33 days reviewed. The humidity was documented out of range 6 of 33 days reviewed.  FLOOR 4  OR 1 The temperature was documented out of range 11 of 33 days reviewed.  OR 2 The temperature was documented out of range 13 of 33 days reviewed.  OR 3 The temperature was documented out of range 31 of 33 days reviewed. The humidity was documented out of range 31 of 33 days reviewed.  OR 4 The temperature was documented out of range 33 of 33 days reviewed.  OR 5 The temperature was documented out of range 14 of 33 days reviewed.  OR 6 The temperature was documented out of range 12 of 33 days reviewed.  OR 7 The temperature was documented out of range 8 of 33 days reviewed.  OR 8 The temperature was documented out of range	A 940			

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A 940	<p>Continued From page 329 31 of 33 days reviewed. The humidity was documented out of range 1 of 33 days reviewed.</p> <p>OR 9 The temperature was documented out of range 12 of 33 days reviewed.</p> <p>OR 10 The temperature was documented out of range 13 of 33 days reviewed. The humidity was documented out of range 2 of 33 days reviewed.</p> <p>OR 11 The temperature was documented out of range 8 of 33 days reviewed.</p> <p>OR 12 The temperature was documented out of range 14 of 33 days reviewed.</p> <p>CATH LAB Review of documents provided by Facilities Engineering department show that temperature and humidity was not being continuously being monitored in Cath Lab 1 and 2. There was no monitoring at all in the sterile storage room that housed sterile pacemaker instruments trays.</p> <p>Staff #S385 confirmed findings regarding on the temperature and humidity ranges in the operating rooms.</p> <p>During an interview on September 26, 2019, after 9:00 a.m. with Staff #S385 the following was confirmed:</p>	A 940		

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A 940	<p>Continued From page 330</p> <p>Staff #S385 confirmed the temperature and humidity was monitored quarterly in Cath Lab 1 and 2 but not continuously. Staff S#385 confirmed there was no monitoring of temperature or humidity in the Cath Lab sterile storage areas that housed sterile pacemaker instrument trays.</p> <p>Review of the AORN Perioperative Standards and Recommended Practices, revealed,</p> <p>"Temperature should be maintained between 68 degrees F to 75 degrees Fahrenheit (20 degrees to 23 C) within the operating room suite. General work areas in sterile processing should be maintained between 68 degrees to 73 degrees F.</p> <p>Relative humidity should be maintained between 20% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas; should be maintained below 60% in sterile storage areas.</p> <p>Review of the facility document titled, "--- Health System - Hospital 1 Hospital, Facility Engineering, Standard Operating Procedure Manual" with an original date of September 2018 revealed the following:</p> <p>"Guideline ---- Health System hospital 1 ensures HVAC systems in critical areas are installed and maintained in a manner that results in the appropriate temperature and relative humidity</p>	A 940			

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A 940	<p>Continued From page 331 ranges for the clinical areas they serve.</p> <p>Purpose: The Engineering Department monitors and control both space temperature and humidity levels in healthcare occupancies within ranges specified TDSHS, CMS, ASHRAE. The building are equipped with controls and instrumentation that automatically adjust the HVAC systems with a goal of maintaining the correct parameters in operating/C-Section rooms, sterile supply locations, and other locations by the hospital ....</p> <p>The temperature and humidity ranges are as specified in ANSI, ASHRAE standard 170-2013 however, to ensure compliance with national standards and best practices, the acceptable humidity range for ---Health System Hospital 1 facility is expanded to include from 20% to 60% RH for all locations."</p> <p>Review of the "Table 7.1 Design Parameters ANSI/ASHRAE/ASHE standard 170-2013 provided by the facility revealed the following:</p> <p>"Operating Room - Design temperature - 68 degrees to 75 degrees Design Humidity - 20-60%"</p> <p>C. TIME OUT</p> <p>During record reviews at the facility from September 23 to September 26, 2019, the following was revealed:</p> <p>The documentation in the surgical chart for the time out did not include all elements of a</p>	A 940			

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A 940	<p>Continued From page 332</p> <p>complete Time Out. Chart reviews completed for Patient #'s 42, 43, 44, 203, 204, 205, and 206, show documentation of the patient identity, correct procedure and site, team members present and in agreement of procedure. There was no documentation in the record that all the activity stopped prior to and during the time out.</p> <p>During an interview with Staff #S695 on September 24, 2019, after 12:00 p.m., Staff #S695 confirmed the documentation was not in the patient medical record.</p> <p>Review of the facility document titled, "Procedural Safety Guide" revealed the following:</p> <p>"Timeout Prior to any invasive action done on patient by the procedure team. All activity stops, music silenced."</p> <p>Review of the facility policy titled, "Universal Protocol - Appendix C - Time Out Process" with an effective date of 5/31/2007 revealed the following:</p> <p>"C. During the Time out, other activities are suspended, to the extent possible without compromising patient safety, so that all members of the team are focused on the active confirmation of the correct patient, procedure, site/site, and other critical elements.</p> <p>D. SANITARY ENVIRONMENT</p> <p>During a tour on September 16, 2019, after 1:00</p>	A 940			

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A 940	<p>Continued From page 333 p.m. the following observations were made:</p> <p><b>CATH LAB #2</b></p> <p>There was a build-up of dust, dirt, and debris on the linoleum in the corners of the room. There were seams in the linoleum flooring that had disintegrated exposing cracks that would harbor bacteria. Several areas in the linoleum flooring had tears, cracks and had separated from the wall.</p> <p>The door and door frame had missing pieces of the frame exposing the wood. There was no way to properly disinfect the frame. The door frame had scrapes and missing paint on the frame. The rubber fatigue mat on the floor was covered in dust, dirt, and debris.</p> <p>There was rust, dirt, hair, and debris around the base of the Cath lab table. The base of the Cath lab table had missing scrapes and chips of paint. There was rust on the surgical metal table wheel casters. There were scrapes and chips of plaster missing on the walls. There was no way to properly disinfect the walls. There was rust on the frame and wheel casters of the linen hamper.</p> <p>There was a rolling step stool that had three steps. The steps were covered in a rubber slip mat. The mat was peeling up and covered in dust, dirt, and debris. The edge of the step outside of the rubber mat was covered rust, dirt, and debris.</p> <p>The Cath Lab table was made with disposable sheets. There was no way to determine if the sheets were clean or dirty. Surveyor lifted the sheets to look under and the mattress had spots</p>	A 940			

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A 940	<p>Continued From page 334</p> <p>of a shiny substance that appeared to be contrast medium. There was a yellow and black spill containment platform. The inside base of the platform was covered in black build up and dust.</p> <p>The supply bins that stored sterile patient supplies were coated in dust, dirt, and debris. There was a vinyl covered lead radiation flap hanging from the Cath Lab table that a tear in the vinyl.</p> <p>There was a sterile patient supply (Mynx vascular closure device) stored in the cabinet that had been opened. The supply was in the cabinet ready for patient use. There was a package of electrodes stored in the cabinet in an open package. Review of the manufacturer precautions on the packaged revealed, "Pre-cautions, do not open package until immediately prior to use."</p> <p>There were three expired Impulse FL4 Angio catheters used in coronary angiograms that expired 6-19, over 3 months ago.</p> <p>The cabinet door had a metal handle that was loose and had been taped to the door to secure the handle. The cabinet stored a mixture of sterile supplies (needles, IV tubing, Micro-puncture kits, radial art lines, suction catheters, sutures) stored with non-sterile supplies (Suction canisters, emesis bags, and oxygen tubing).</p> <p>There was a cabinet that had sterile Angio catheters used in coronary angiograms. The catheters were stored in a manner that allowed the bottom of the catheters to touch the base of the cabinet and hang out of the cabinet when the door was open. The base of the cabinet was coated in dust, dirt, and debris. There was a bin</p>	A 940			

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A 940	<p>Continued From page 335</p> <p>containing sterile IV tubing. There was a bin on top that had fallen into the bin of sterile IV tubing and was sitting on top of the sterile supplies.</p> <p>There was a drawer that contained a syringe out of the manufacturer package and was laying in the drawer. The drawer contained lab supplies (blood collection tubes and vacutainers) and was stored with boxes of batteries.</p> <p>There was a Hemochron machine that tested ACT (Activated Clotting Time). The lab test is used to monitor high doses of unfractionated (standard) therapy which slows the ability of the blood to clot. Sitting next to the Hemochron machine on the cabinet was a plastic quality check probe. The probe was used daily to check the accuracy of the Hemochron machine. The probe was broken and taped together on the back. Underneath the tape there was a build-up of dirt and debris.</p> <p>During a patient tracer on September 17, 2019, after 11:00 a.m. the following observations were made:</p> <p>Staff #S391 was observed completing a prep. Staff #S391 used a Chloraprep to prep the chest area for a pacemaker procedure. Staff #S391 went back and forth from the surgical site to the periphery several times while prepping.</p> <p>Review of the manufacturer IFU for Chloraprep revealed the following:</p> <p>"Once the solution is visible on the skin, completely wet the treatment area with the antiseptic using gentle back and forth strokes.</p>	A 940			



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A 940	<p>Continued From page 336</p> <p>Progress from incision site to the periphery of the surgical field ..."</p> <p>After the patient had been prepped and draped, Staff#S102 raised the drape and went under the drape to check the IV site on the opposite side of the bed. Staff #S102 caused the drape to tent, and the hemostats and suction tubing already attached to the drape where flapping risking contamination to the field.</p> <p>Observed IV tubing on the floor. Staff #102 stepped on the IV tubing and then proceeded to wipe it off with a Sani-wipe.</p> <p><b>CATH LAB SUPPLY ROOM</b></p> <p>There was a storage rack with boxes of corrugated boxes that had sterile Micro-puncture kits stored in them. The boxes were sitting next to sterile Swan-Ganz kits (a sterile catheter used to monitor the heart's function and blood flow). There were unsterile supplies (patient urinal) stored next to the Swan-Ganz kits. The shelves on the storage racks were coated in tape residue.</p> <p>There was a bin observed on a shelf that had sterile instruments in it. The bin had sterile peel packs (surgical sterilization pouches) in the bottom of the bin. There were sterilized wrapped items sitting on top of the peel packs. The peel packs that were stored were crushed, bent and wrinkled. There was no way to ensure the sterility of the item. The bin contained multiple peel packs that had water stains on the package. There was a "Vis-U-All Self Seal Cath Lab Connector" in a sterile peel pack that had water stains and was sterilized in 1998, over 20 years ago. There was a</p>	A 940			

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A 940	<p>Continued From page 337</p> <p>"Interrogator Pacemaker cable" stored in a sterile peel pack that was crushed, wrinkled and had water stains on it. The pacemaker was sterilized in 2011, over 8 years ago. There was a sterile Medtronic pacemaker cable that expired 6-26-2011, over 8 years ago. The base of the bin was coated in dust, dirt, and debris. The base of the bin also had a dead bug in it.</p> <p>The bins on the shelves containing sterile and non-sterile supplies were coated in dust, dirt, and debris. There was corrugated cardboard boxes that had sterile patient supplies (Micro-Introducer Kits) stored in them. There was a dolly stored in the room that was coated in rust.</p> <p>Review of ANSI/AAMI S179:2017 - Comprehensive guide to steam sterilization and sterility assurance in health care Facilities Engineering department revealed the following:</p> <p>"11 Storage and transportation</p> <p>11.1 Sterile storage 11.1.I Storage Facilities (Engineering department)</p> <p>Sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.</p> <p>Sterile storage areas should be kept clean and dry.</p> <p>Sterile items should be</p> <p>1) stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes;</p>	A 940			

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A 940	<p>Continued From page 338</p> <p>2) stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls;</p> <p>3) stored in such a way that wrapped packages are not stored beneath rigid sterilization containers on the same shelf; and</p> <p>4) positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised."</p> <p>Review of the AORN (Association of perioperative Registered Nurses) 2019 Perioperative Standards and Recommended Practices, Guidelines for Sterilization, revealed the following:</p> <p>"...Recommendation IV.c. Supplies and equipment should be removed from external shipping containers and open-edged corrugated cardboard boxes before transfer to the sterile storage area or point of use.</p> <p>External shipping containers and open-edged cardboard boxes may collect dust, debris, and insects during shipment and may carry contaminants into the surgical suite ..."</p> <p>Review of ANSI/AAMI ST79:2017 revealed the following:</p> <p>"11.1 Sterile Storage</p> <p>Sterile items should be stored under environmentally controlled condition that reduces</p>	A 940		

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A 940	<p>Continued From page 339 the potential for contamination ...</p> <p>Supplies should be removed from external and web-edged shipping container before transport to any restricted area ..."</p> <p><b>CATH LAB FAMILY WAITING ROOM</b></p> <p>The chairs in the family room had crevices that were full of food crumbs, dirt, dust, and debris. There was food underneath the chairs that appeared to be an old French fry. There was scrapes and chips of paint missing that exposed the plastic on the walls. There was rust on the metal ceiling frames. The window seal had water stains and a circular brown stain that appeared to be from a soda can.</p> <p>Staff ##310 confirmed the findings on the Cath lab.</p> <p><b>STERILE PROCESSING CLEAN PREPARATION AREA</b></p> <p>During a tour on September 17, 2019, after 1:00 p.m. the following observations were made:</p> <p>Staff #S392 was observed putting an instrument set from the oral clinic together. Observed rust on instruments (stringer 1 &amp; 2 tooth extractors). The set was ready for packaging and sterilization and Staff #S392 did not recognize the rust on the instruments.</p> <p>There were several metal carts in the preparation room. Staff #S58 stated that some of the carts were made available for outside vendor reps to</p>	A 940			

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A 940	<p>Continued From page 340</p> <p>stock and store instruments and implants for the sets that were stored at the facility. Also, some of the carts contained surgical supplies and instruments. The carts observed were as follows:</p> <p><b>RED CART</b> The red cart contained unsterilized Synthes implants used to restock the surgical trays. The cart had a rubber top covered in dust and debris. There was a drill bit in the crevice on the top of the cart.</p> <p><b>BLUE CART #1</b> The cart contained glass medicine cups, stringer instrument holder, dust covers, and misc. supplies. The top of the cart had a plastic covering that was broken, and pieces of the plastic were missing on the corners. There was no way to properly disinfect the covering. Inside the cart, the base of the drawer was covered in rust, dust, dirt, and debris. The metal drawer glides that hold the drawer in place were covered in rust. The base frame of the cart had scrapes of paint missing and was covered in rust. There was no way to properly disinfect the cart.</p> <p><b>RED ZIMMER CART</b> The cart contained eye instruments. There were bins that contained metal surgical pins. The base of the bins was covered in dust and debris. The top of the cart had a plastic covering that was broken and pieces of the plastic were missing on the corners. There was no way to properly disinfect the covering.</p> <p><b>BLUE CART #2</b> The cart contained Biomet, Zimmer, Synthes, and Smith &amp;Nephew instruments and supplies. The base of the cart was covered in rust.</p>	A 940			

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A 940	<p>Continued From page 341</p> <p>The floor in front of the autoclaves and next to the metal carts storing extra surgical instruments had chips of cement missing. There were several holes in the cement floor that exposed the subfloor.</p> <p><b>STERILE PROCESSING INSTRUMENT STORAGE ROOM</b></p> <p>There was a metal rack in the storage room that stored Neurological instruments. The bottom shelf had two splash guards pieced together. There were several gaps in areas that would allow contamination and splashing of the instruments when the floor was mopped.</p> <p>There were several instrument sets (Plastic Tram Extras, GU XLARGE Male Urethral sounds, and Synthes Loaner trauma ortho) that had a faded external chemical indicator on the set. The external chemical indicator was faded and there was no way externally to determine if the items had been exposed to the sterilization process.</p> <p>There was a Depuy loaner instrument. The peel pack had a total of three peel packs, two on the inside and one external. There was a radial head instrument sterilized inside a double peel pack. The inside peel pack was folded in on several corners. There was a Biomet Screw removal instrument sterilized inside a double peel pack. The inside peel pack was folded in several places. The external package had several stains on the outside of the package that appeared to be water stains.</p> <p>The sterilization packaging was not done in a</p>	A 940			

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A 940	<p>Continued From page 342</p> <p>manner that would allow sterilization of the contents.</p> <p>Review of the AORN (Association of perioperative Registered Nurses) 2019 guidelines revealed the following:</p> <p>"V. Chemical indicators specific to the sterilization method selected should be used with each package. Chemical indicators are used to verify that one or more of the conditions necessary for sterilization have been achieved within each package. External and internal CIs do not verify sterility of the contents.</p> <p>V.a A CI should be placed on the outside and inside of every package to be processed unless the internal indicator is readable through the package material. External CIs are used to verify that the package has been exposed to the sterilization process. External indicators are intended to differentiate processed packages from unprocessed packages. Internal CIs are used to verify that the sterilant has reached the contents of the package and that critical variables of the sterilization process have been met. The number of critical process variables that are monitored with an internal indicator is dependent on the specific type of internal indicator that is used.</p> <p>V.a.1. A class I CI (i.e., process indicator) should be placed externally. Examples of process indicators are indicator tape and indicator labels."</p> <p>Review of AORN 2019 guidelines for packaging</p>	A 940		

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A 940	<p>Continued From page 343 revealed the following:</p> <p>"VII.d. Unless otherwise specified in the manufacturer's IFU, when double pouching is used, the inner pouch should fit within the outer pouch without folding, and the inner pouch should face in the same direction as the outer pouch (i.e., plastic or Mylar faces plastic or Mylar, and paper or Tyvek faces paper or Tyvek).</p> <p>Folding the inner pouch may entrap air and inhibit sterilant contact.</p> <p>The plastic side of the pouch is impervious to sterilant penetration. The paper side of the pouch permits sterilant penetration. Facing the inner pouch in the same direction as the outer pouch results in paper-to-paper contact through which the sterilant can penetrate. If the paper side of the inner pouch is in contact with the plastic side of the outer pouch, penetration of the sterilant through the paper side of the inner pouch is prevented."</p> <p>Staff #S58 confirmed the above findings in the sterile processing department.</p> <p>FLOOR 3 - SURGERY</p> <p>HALLWAY</p> <p>During a tour on September 18, 2019, after 1:00 p.m. the following observations were made:</p> <p>There was a cleaning cart in the hallway next to the epidural cart cove. There was a scoop used</p>	A 940			



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A 940	<p>Continued From page 344</p> <p>to pick up debris in the Operating Room (OR). The scoop had not been cleaned and was stored on the cart covered in dirt and debris. On the shelves of the cart there was a corrugated cardboard box that had plastic trash bags in it. On the bottom shelf, there was suction canisters and tubing to restock in the surgical rooms. The base of the shelf was covered in dust and debris. The top of the cart had a cushioned matt covering. The covering had tears in it. There was no way to properly disinfect the covering.</p> <p>There was a cove next to the charting area that had scrapes and missing chips of paint exposing the plaster. The outside corner had missing plaster on the wall.</p> <p>OR 15</p> <p>There was a cooler that contained blood products sitting on the floor. Staff #S383 was asked if the room had been cleaned. Staff #383 stated, "Yes, it has." Staff #S383 was asked how long the blood products had been in the room and what case the products were from. Staff #383 stated she would check. Staff #384 was called to the room. Staff #384 was asked what case the blood products were from. Staff #384 stated "The blood products were from a previous case this morning." Staff #S383 was asked what time the case completed. Staff #383 stated, "11:24 am." The blood was found in a cooler on the OR floor almost two hours after the case completed. Staff #S384 was asked what the protocol was for returning unused blood products to the lab. Staff #S384 stated that blood products should be kept with the patient they were issued for or returned to the lab when the case was completed if they</p>	A 940			

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A 940	<p>Continued From page 345</p> <p>were no longer needed. Staff #S383 confirmed, the blood products were left in the OR room unattended for almost 2 hours and housekeeping had cleaned the room with the cooler of blood sitting on the floor.</p> <p>The suction canisters in the room had splashes of red substance that appeared to be blood. There was rust on the wheel casters of the linen cart. The linen cart had scrapes and missing chips of paint. There was no way to properly disinfect the cart. The wall tiles had cracks and chips of tile missing. The fluid warmer had rust in the basin. The base of the fluid warmer pole had missing areas of the top protective covering. The IV pole for the Hot Line warmer had rust on the base.</p> <p>The OR table mattresses were pulled back for observation. The mattress had been placed back on the table and covered in sheets while the underneath of the mattress was wet. The mattress was still wet during observation.</p> <p>The anesthesia cart had sterile esophageal stethoscopes and urethral catheters stored on the side of the cart in front of the black medication wastage container. There was no way to prevent contamination of the sterile supplies from splashes to the medication wastage container. The anesthesia cart had sterile intubating stylet supplies with a rubber band tightly woven around them. Physical damage to the package, such as holes and tears can be caused by compression of the package.</p> <p>The main door to the OR had broken and chips of the door missing that exposed the wood. There was no way to properly clean the door with exposed wood.</p>	A 940			

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A 940	Continued From page 346  L&D (LABOR AND DELIVERY) STORAGE ROOM  There were cabinets that stored sterile patient supplies (Sutures) coated in dust and debris. The counters in the room had a mixture of sterile supplies (Surgical gowns and Intravenous tubing sets) and non-sterile supplies (Pathology biohazard formalin specimen cups) stored in-between them.  The floor had a buildup of dust, dirt, debris, and dead bugs in the corners of the room. There was water stains and rust on the linoleum in the room. There were seams in the linoleum flooring that had disintegrated exposing cracks that would harbor bacteria.  There was a PPH (Post-Partum Hemorrhage) cart that contained sterile vaginal packing packages stored with a rubber band tightly woven around them. Physical damage to the package, such as holes and tears could be caused by compression of the package. There was a sterile post-partum balloon used to stop post-partum hemorrhage folded and stuffed in a cart. The sterility of the package was compromised by the method of storage. There was a cart in the storage room that contained sterile and non-sterile supplies. The drawers in the cart had supplies hanging out of the bins caused from over stocking exposing the sterile items to damage of the packaging. The base of the bins was coated in dust, dirt, and debris.  Staff #S124 confirmed the findings for L&D. Staff #S388 confirmed the findings for anesthesia	A 940			

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A 940	<p>Continued From page 347 supplies.</p> <p>OR #6</p> <p>The OR table mattresses were pulled back for observation. The mattress had been placed back on the table and covered in sheets while the underneath of the mattress was wet. The mattress was still wet during observation.</p> <p>The trash can in the room contained trash. There was a glove and a pipe cleaner that appeared to be covered in blood. Staff #S382 was asked if the room had been cleaned. Staff #S382 confirmed it had been.</p> <p>There was rust on the IV pole. There was a build-up of dust, dirt, debris, and hair in the corners of the room.</p> <p>There were seams in the linoleum flooring that had disintegrated exposing cracks that would harbor bacteria. There was a shiny substance on the floors in several areas.</p> <p>There were rubber mats outside the OR at the scrub sinks that were covered in dirt and debris. Underneath the mats there were rust stains on the linoleum floor indicating that the mats were placed on wets floors.</p> <p>Staff #S100 confirmed the findings in OR#6.</p> <p>GI LAB #3</p> <p>During a tour on September 19, 2019, after 9:00 a.m. the following observations were made</p>	A 940			

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A 940	<p>Continued From page 348</p> <p>There was an anesthesia cart that had scrapes and missing chips of paint. The handles on the cart had a plastic covering. The plastic covering was cracked. Underneath the plastic covering there were black stains and rust. The base frame of the anesthesia cart had scrapes and missing chips of paint. The IV pole had scrapes and missing chips of paint. The cabinets had bins storing patient supplies (CO2 monitor) that were coated in dust, dirt, and debris in the base of the bins.</p> <p>There were seams in the linoleum flooring that had disintegrated exposing cracks that would harbor bacteria. There was a shiny substance on the floors in several areas.</p> <p>The cabinets had corrugated cardboard boxes that stored PPE (Personal Protective Equipment) gowns used in Gastroenterology procedures.</p> <p>There was a sterile endotracheal tube stored with the package bent, wrinkled, and crushed. There was no way to ensure the sterility of the item.</p> <p>The GI travel cart used to perform bedside gastroenterology procedures had scrapes and missing chips of paint. Inside the drawers there was a mixture of sterile (patient sponges, syringes) and non-sterile (biohazard bags, solidifier and tourniquets) stored in the same drawer. There was rust on the handle of the cart.</p> <p>There were scrapes and missing chips of paint exposing the plaster on the wall next to the physician computer station. On the floor below the wall, the linoleum had cracks and missing pieces exposing the subfloor. There was no way</p>	A 940			

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A 940	<p>Continued From page 349 to properly clean the floor.</p> <p>Staff #S57 confirmed the findings in the GI Lab.</p> <p>MAIN OR - FLOOR 4</p> <p>During a tour on September 23, 2019, after 12:00 p.m. the following observations were made:</p> <p>OR#7</p> <p>There was a dirty laundry hamper store next to sterile supplies (Central Line insertion kits). There was a Sharps container stored (zip tied) to a rack that contained sterile supplies (Central line catheters, &amp; IV tubing).</p> <p>The anesthesia cart had sterile esophageal stethoscopes and urethral catheters stored on the side of the cart in front of the black medication wastage container. There was no way to prevent contamination of the sterile supplies from splashes to the medication wastage container. The anesthesia cart had sterile intubating stylet supplies with a rubber band tightly woven around them. Physical damage to the package, such as holes and tears can be caused by compression of the package.</p> <p>While room was being cleaned, observed Staff #S696 walk in blood on the floor with no shoe covers on. Staff #696 continued cleaning the room, at times going in and out of the room with the same shoes on.</p> <p>OR #11</p>	A 940			

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A 940	<p>Continued From page 350</p> <p>The anesthesia cart had sterile esophageal stethoscopes and urethral catheters stored on the side of the cart next to a sharps container. The anesthesia cart had sterile intubating stylet supplies with a rubber band tightly woven around them. Physical damage to the package, such as holes and tears could be caused by compression of the package. There was a Sharps container stored (zip tied) to a rack that contained sterile supplies (Central line catheters, &amp; IV tubing). The anesthesia cart was mounted to the wall by a wood plank. The wooden plank was missing a trim piece of laminate that exposed wood. There was no way to properly decontaminate the wood. The anesthesia cart had scrapes and missing chips of paint. The base frame of the anesthesia cart had scrapes and missing chips of paint. The handles on the cart had a plastic. The plastic covering was cracked. Underneath the plastic covering there were black stains and rust. The wall tiles had cracks and chips of tile missing. The base of the IV pole was coated in rust. There was a metal cart storing IV supplies that was coated in rust.</p> <p>EQUIPMENT STORAGE COVE AREA - OUTSIDE OR #3</p> <p>There was an anesthesia machine that had yankauer suction tubing hanging from the machine. There was no way to determine if the tubing was clean or dirty. There was a spine/back table stored in the cove that had rust on the frame. There was an orthopedic surgical table extension stored in the cove leaned against the wall. The area of the wall that the orthopedic table was leaning against had missing scrapes and chips of paint exposing plaster.</p>	A 940			

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A 940	<p>Continued From page 351</p> <p>In the hallway outside of the cove, there were several racks storing equipment. The fluid warmer stored in that area had rust in the basin.</p> <p>Staff #'s S55, S56, S382, and S695 confirmed the findings in the OR.</p> <p><b>ANESTHESIA WORK ROOM</b></p> <p>There was missing laminate on the trim of the shelves storing patient supplies exposing wood. There was no way to properly decontaminate the area. There was rust on the metal frames of the chairs in the room.</p> <p><b>COVE OUTSIDE ANESTHESIA WORK ROOM</b></p> <p>There was a cart used to restock the OR rooms that had a mixture of sterile (Laryngeal blades and Endotracheal tubes) with non-sterile supplies (suction canisters, solidifier, suction tubing extension, and cleaning supplies) on the same shelf.</p> <p>The was an anesthesia cart used to store patient supplies that had rust on the base of the frame.</p> <p>There was an area behind the anesthesia cart on the wall that had holes and indentions in the wall that exposed plaster. There was no way to properly decontaminate the wall.</p> <p>Staff #S388 confirmed the findings for anesthesia.</p>	A 940			



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A 940	<p>Continued From page 352 SUB-STERILE BETWEEN OR 11 AND OR 12</p> <p>The wall corner had scrapes and missing chip paint exposing the plaster, wall had multiple areas that had scrapes of paint exposing plaster. There was no way to properly disinfect the walls.</p> <p>Staff #S56 confirmed the findings for the sub-sterile area.</p> <p>During a tour on September 24, 2019 after 11:00 p.m. the following observations were made:</p> <p><b>STERILE CORE AREA</b></p> <p>There was a cart that contained instruments for (EUA) airway examinations. Staff #432 stated, the instruments on the cart were processed by sterile processing department. The instruments were sterilized and then transported back to the cart. Staff #432 stated that at the time the instruments were delivered to the cart, the instruments were removed from the sterile peel packs and put into the cart drawers. There was no way to determine if the instruments in the cart were clean or dirty. The instruments were laying in the drawer unlabeled with no indication of clean or dirty. The cart was unsecured and there was no way to ensure the instruments in the cart were no handled and contaminated after being placed in cart.</p> <p>Review of the facility process hanging on the side of the cart revealed the following:</p> <p>"1. Stryker personnel will sanitize hands and don clean gloves prior to placing sterilized airway</p>	A 940			

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A 940	<p>Continued From page 353</p> <p>instruments in the airway cart. Instruments must be transported in a clean bag if transported manually or on the clean dumbwaiter.</p> <p>2. Stryker personnel will unwrap sterile airway instruments and place in the airway cart ..."</p> <p>Staff #S56 and #S432 confirmed the findings on the EUA cart.</p> <p>HOSPITAL #1</p> <p>A. CATH LAB SUPPLY ROOM</p> <p>During a tour on September 16, 2019, after 2:00 PM the following observations were made:</p> <p>There was a wire storage rack with 6 Mayo trays wrapped in the blue sterilizations wrap with Transesophageal Echocardiogram Endoscope (TEE) coiled in the sterilization wrapper. Two of the of the wrapped TEE probes were open with no date as to when the TEE probes had been disinfected. The other 4 TEE probes had disinfection dates of.</p> <ol style="list-style-type: none"> <li>1. 8/2018 (no specific day)</li> <li>2. 8/21/2019</li> <li>3. 9/6/2019</li> <li>4. 9/11/2019</li> </ol> <p>The 6 TEE were being stored on the bottom shelf of the wire rack. The barrier on the bottom rack did not completely cover the bottom rack allowing splatter from the sweeping and mopping of the room. Also, the sterilization wrap was not tight, which allowed contamination of the TEE probes. The sterilization tape was faded, peeling off, and broken on some of the mayo trays that the TEE</p>	A 940			

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A 940	<p>Continued From page 354 probes were wrapped in.</p> <p>An interview with Staff #S310 on 9/16/2019 revealed that she was not knowledgeable in the proper way to store the Transesophageal Echocardiogram Endoscope (TEE) probes.</p> <p>There was no temperature and humidity being monitored of the storage room that held the TEE probes.</p> <p>A review of the facility log for disinfection titled, "HLD DOCUMENTATION LOG" the months of June, July, August, and September 2019 revealed the following:</p> <p>The TEE probes were used:</p> <p>June 2019- 21 times July 2019- 22 times August 2019- 28 times September 2019-17 times</p> <p>The facility has two brands of TEE probes Phillips and General Electric.</p> <p>A review of the manufacture guidelines for Philips "Care and Cleaning of Ultrasound Systems and transducer revealed the following:</p> <p>"Avoid storing transducers in areas of temperature extremes or in direct sunlight.</p> <p>Store transducers separately from other instruments to avoid inadvertent transducer damage.</p> <p>Before storing transducers, make sure they are</p>	A 940		

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A 940	<p>Continued From page 355 thoroughly dry.</p> <p>For TEE transducers, be sure the distal tip is straight and protected before storing the transducer.</p> <p>Never store a TEE transducer in the carrying case, except to transport it."</p> <p>A review of the manufacture guidelines for General Electric Technical publications TEE probes revealed the following:</p> <p>"1. Following the last procedure and cleaning/disinfection of the day, take extra care to dry the TEE Probe with a clean cloth.</p> <p>2. Do not use the shipping case or any closed container for other than short term storage or to ship the probe from one place to another. When the shipping case is used for these purposes, avoid damage to the probe by allowing nothing to protrude beyond the case when closing the lid. Make sure that the probe is stored dry. Storing the probe in any liquid will damage the endoscope.</p> <p>3. The probe should be stored in a vertical orientation on a Storage rack. The handle should be stored so that the flexible shaft is pointing down and is hanging freely (Figure 1-23). Avoid direct sunlight, and exposure to x-rays. Recommended storage temperature range: Between 0 C and +45°C."</p> <p>When not in use, store endoscopes freely hanging vertically to aid drying. Do not store is closed containers or where condensation might</p>	A 940			

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A 940	<p>Continued From page 356</p> <p>occur. The probe shipping case is not recommended for storage between exams. Keep away from dirty endoscopes to prevent cross Contamination. Please refer to the User Manual for further Information."</p> <p>A review of the facility's policy titled, "Pre-Cleaning, Sterilization, High and Low-level disinfection, and Storage of the processed patient care devices" revealed the following:</p> <p>"APPENDIX M, STORAGE AND TRANSPORTATION OF PATIENT CARE MEDICAL DEVICES AND OTHER PATIENT CARE ITEMS AFTER STERILIZATION OR HIGHLEVEL DISINFECTION</p> <p>A. Scopes should be hung upright in a covered cabinet for storage after processing.</p> <p>B. If scopes are transported to another area for storage, they may be transported in a rigid container."</p> <p>An interview with Staff #310 on 9/16/2019 revealed, the TEE probes were not disinfected and stored per the manufacturer guidelines. Also, the facility staff was not following the policy on "Pre-Cleaning, Sterilization, High and Low-level disinfection, and Storage of the processed patient care devices.</p> <p>D. SANITARY ENVIRONMENT</p> <p>During a tour on September 16, 2019, after 1:00 p.m. the following observations were made:</p>	A 940			

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A 940	<p>Continued From page 357 CATH LAB #1</p> <p>There was a build-up of dust, dirt, and debris on the linoleum in the corners of the room. There were seams in the linoleum flooring that had disintegrated exposing cracks that would harbor bacteria. Several areas in the linoleum flooring had tears, cracks and had separated from the wall.</p> <p>The door and door frame had missing pieces of the frame exposing the wood. There was no way to properly disinfect the frame. The door frame had scrapes and missing paint on the frame. The rubber fatigue mat on the floor was covered in dust, dirt, and debris.</p> <p>There was rust, dirt, hair, and debris around the base of the Cath lab table. The base of the Cath lab table had missing scrapes and chips of paint. There was rust on the surgical metal table wheel casters. There was scrapes and chips of plaster missing on the walls. There was no way to properly disinfect the walls.</p> <p>The was rust on the frame and wheel casters of the linen hamper. There was a rolling step stool that had three steps. The steps were covered in a rubber slip mat. The mat was peeling up and covered in dust, dirt, and debris. The edge of the step outside of the rubber mat was covered rust, dirt, and debris.</p> <p>The supply bins that stored sterile patient supplies were coated in dust, dirt, and debris. There was a corrugated box with the lid torn off that had cables stored in the box. The box had an expiration date of 11/28/2008.</p>	A 940		

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A 940	<p>Continued From page 358</p> <p>There was screen radiation door with vinyl covered lead that was discolored at the bottom of the screen.</p> <p>There were expired Epinephrine 1 MG medications with expiration dates of 3/2019 and 5/2019 in the metal medication cabinet on the wall. The medication cabinet was not secured.</p> <p><b>CATH LAB STORAGE AREA ON THE BACK HALLWAY</b></p> <p>On the back hallway there were blood pressure machines and vein Doppler machines but there was no way to know if the equipment was clean or dirty.</p> <p>There was an ultrasound machine sitting on the back hallway that had a PM (preventive maintenance) sticker that expired 4/2019.</p> <p>In the storage room area there was a dead bug in the light fixture.</p> <p>In the pericardiocentesis cart there were water stained peel packs with instruments.</p> <p>There was a red metal oxygen tank holder that was dirty and rusted in the storage room.</p> <p><b>BRONCHOSCOPY ROOM</b></p> <p>During a tour on September 17, 2019, at 10:30 AM the following observations were made:</p> <p>In the decontamination room observed clean gloves, mask, and gowns located on the counter</p>	A 940			

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A 940	<p>Continued From page 359</p> <p>in the splatter zone of when staff clean the dirty scopes.</p> <p>There were clean and sterile supplies mixed together on the shelves with sterile supplies being on the bottom shelf. There were urinals on the shelf with sterile packs. Also, there were corrugated boxes on the sterile supply shelf.</p> <p>Observed on the floor was a sterile urine specimen cup.</p> <p>The drip pan for the bronchoscopy scopes was stained with multiple dark water stains.</p> <p>The bottom shelf of the plastic linen hamper was cover in dust particles.</p> <p><b>STERILE PROCESSING CLEAN PREPARATION AREA</b></p> <p>During a tour on September 17, 2019, at 11:31 AM the following observations were made:</p> <p>There was a drain system on the clean side for the washers when the instruments came out. The drain system had clear plastic tubing with four loops. The first loop had large amount of black substance build-up with stagnated water. The plastic tubing was not draining the water. The second loop had pink color with the black substance and water was lying in the tubing. The third loop was the dead-in loop and there was water sitting in the loop.</p> <p>The large sterilizers had unclean appearance. There were multiple pieces sterilization tape and load stickers stuck to the wall of the sterilizer.</p>	A 940			



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A 940	<p>Continued From page 360</p> <p><b>STERILE PROCESSING DECONTAMINATION AREA</b></p> <p>During a tour on September 17, 2019, after 1:00 p.m. the following observations were made:</p> <p>There were multiple wash carts that connect to the washer. The carts were discolored with residue and small trash particles from the dirty instrument trays. On the carts were small white containers where the water would drain from the washer cart. The small containers were over filled and spilling to the bottom shelf and onto the floor.</p> <p><b>STERILE INSTRUMENT STORAGE ROOM</b></p> <p>During a tour on September 18, 2019, after 10:16 AM, the following observations were made:</p> <p>In the storage room, there were multiple corrugated cardboard boxes filled with surgical packs. Also, the room contained surgical packs that were stacked on the shelves in the same room with all the corrugated cardboard boxes.</p> <p>Review of the AORN (Association of perioperative Registered Nurses) 2019 Perioperative Standards and Recommended Practices, Guidelines for Sterilization, revealed the following:</p> <p>"...Recommendation IV.c. Supplies and equipment should be removed from external shipping containers and open-edged corrugated cardboard boxes before transfer to the sterile storage area or point of use.</p>	A 940			

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A 940	<p>Continued From page 361</p> <p>External shipping containers and open-edged cardboard boxes may collect dust, debris, and insects during shipment and may carry contaminants into the surgical suite ..."</p> <p>Review of ANSI/AAMI ST79:2017 revealed the following:</p> <p>"11.1 Sterile Storage</p> <p>Sterile items should be stored under environmentally controlled condition that reduces the potential for contamination ...</p> <p>Supplies should be removed from external and web-edged shipping container before transport to any restricted area ..."</p> <p>FLOOR 3 - SURGERY</p> <p>During a tour on September 18, 2019, after 1:00 p.m. the following observations were made:</p> <p>OR #14</p> <p>The suction canisters in the room had splashes of red substance that appeared to be blood. There was rust on the wheel casters of the linen cart, mayo stand, IV pole, and the surgical back table. There was no way to properly disinfect the equipment that was covered in rust. The wall tiles had cracks and chips of tile missing.</p> <p>The OR table mattresses where pulled back for observation. The mattress had been placed back</p>	A 940		

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A 940	<p>Continued From page 362</p> <p>on the table and covered in sheets while the underneath of the mattresses was wet. The mattress was still wet during observation.</p> <p>The anesthesia cart had sterile esophageal stethoscopes and urethral catheters stored on the side of the cart in front of the black medication wastage container. There was no way to prevent contamination of the sterile supplies from splashes to the medication wastage container.</p> <p>The main door to the OR had broken and chips of the door missing that exposed the wood. The main door to the OR was broken and had chips around the door frame that was missing which exposed the wood.</p> <p>OR#13</p> <p>In the ante room, off OR#13 there was blood on the floor in three different areas. It appeared a staff member had gone to the fluid warmer for supplies with bloody shoes. OR#13 had already been cleaned.</p> <p>Staff #S124 confirmed the findings for Labor &amp; Delivery</p> <p>SURGERY STORAGE AREA</p> <p>There were four Transvaginal probes stored coiled up in a hard-plastic container. The probes were not stored in a manner that would protect them from damage or contamination and that was consistent with national guidelines and manufacturers' recommendations such as hanging vertically in a cabinet and storing in a</p>	A 940			

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A 940	<p>Continued From page 363</p> <p>clean environment. The surgical staff that were interviewed were not knowledgeable in proper way to store the transvaginal probes.</p> <p>There was no temperature and humidity being monitored of the storage room that held the Transvaginal probes.</p> <p>Staff #S56 confirmed the findings in the storage room.</p> <p><b>ANESTHESIA STORAGE AREA ON 3RD FLOOR</b></p> <p>There were multiple anesthesia laryngoscope blades piled in a blue plastic bin in the storage room. There was no way to know if the blades were clean or dirty. Also, there were piles of laryngeal mask airway (LMA'S) not labeled or numbered to know if the LMA's were suitable to be re-sterilized. Further observation revealed corrugated cardboard boxes mixed with the clean and sterile supplies.</p> <p>Staff #S388 confirmed the findings in the anesthesia storage room.</p> <p>During the tour of the 3rd floor, observed a staff member bring a IV pole in the back hallway. Surveyor asked if the IV pole was clean and she stated "Yes". The surveyor asked did you bring the pole down the hallway and up the elevator with patients and visitors. She stated "Yes".</p> <p><b>GI LAB PROCESSING ROOM</b></p> <p>During a tour on September 19, 2019, after 10:10</p>	A 940			

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A 940	<p>Continued From page 364</p> <p>AM the following observations were made:</p> <p>The front side of processing sinks were rusted and stained with rust marks running down the side of the sink. Along the side of the sink and the counter observed more rust.</p> <p>The processing room was very small, there was only 27 inches between the designated clean and the designated dirty area. There was no door on the decontamination room where the scopes were being processed.</p> <p>A review of the 2019 AORN standards guideline revealed the following:</p> <p>"A minimum of 3 ft (0.9 m) between the decontamination area and the clean work area and either a separating wall or a barrier that extends a minimum of 4 ft (1.2 m) above the sink rim to separate soiled work areas from clean work areas. Cross contamination can result when soiled items are placed in close proximity to clean items or are placed on surfaces upon which clean items are later placed. Separation of the contamination area from the clean area minimizes the potential for contamination of clean and processed flexible endoscopes.</p> <p>Contaminated water droplets had the ability to travel a distance of 39.4 inches (1 m). There is no evidence to indicate that contaminated water droplets from endoscope cleaning activities would be dispersed farther than 39.4 inches (1 m). It is unlikely that microorganisms would be disseminated by air over longer distances because they would be contained within water droplets.</p>	A 940			

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A 940	<p>Continued From page 365</p> <p>The endoscopy processing room should include a door that provides access to and from the decontamination area or decontamination room and a separate door that provides access to and from the clean area or clean workroom."</p> <p>Staff #S393 confirmed the findings in the GI processing room.</p> <p>MAIN OR - FLOOR 4</p> <p>During a tour on September 23, 2019, after 12:00 PM the following observations were made:</p> <p>MAIN OPERATING ROOM HALLWAY</p> <p>On the airway cart at the bottom of the cart there were dust particles.</p> <p>The Stryker camera and video cart on the bottom shelf observed to have dust and dirt particle build-up.</p> <p>OR #9</p> <p>The anesthesia cart had sterile esophageal stethoscopes and urethral catheters stored on the side of the cart and in front was red Sharps container attached to the anesthesia wire cart that contained anesthesia sterile supplies. There was no way to prevent contamination of sterile supplies due to splashes from the wastage container.</p> <p>The handles on the anesthesia cart had a plastic</p>	A 940		

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A 940	<p>Continued From page 366 covering. The plastic covering was cracked. Underneath the plastic covering there were black stains and rust. The wall tiles had cracks and chips of tile missing. The base of the IV pole was coated in rust. The paddles to the Nero equipment had large paint chips and rust.</p> <p>STERILE CORE AREA</p> <p>The clean cardiovascular probes (four) were being stored and coiled in a hard plastic container.</p> <p>A review of the facility's policy titled, "Pre-Cleaning, Sterilization, High and Low-level disinfection, and Storage of the processed patient care devices" revealed the following:</p> <p>"APPENDIX M, STORAGE AND TRANSPORTATION OF PATIENT CARE MEDICAL DEVICES AND OTHER PATIENT CARE ITEMS AFTER STERILIZATION OR HIGHLEVEL DISINFECTION</p> <p>A. Scopes should be hung upright in a covered cabinet for storage after processing.</p> <p>B. If scopes are transported to another area for storage, they may be transported in a rigid container."</p> <p>Staff #S56 confirmed the findings in the Main Operating room areas.</p> <p>HOSPITAL #2</p> <p>A. An observation tour of the OR Department was</p>	A 940			

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A 940	<p>Continued From page 367</p> <p>conducted on 9/20/2019, after 9:20 AM, with Staff #S204, #S215, and #S216. Staff #S279 was observed opening sterile supplies in OR #1 and preparing for a surgical case.</p> <p>An interview was conducted with Staff #S279 on 9/20/2019 after 9:20 AM. Staff #S279 was asked what the temperature and humidity were in the OR before she began to open the sterile supplies. Staff #S279 said, "I don't know but I guess someone would have told me if it was not right." Staff #S279 was asked what the temperature and humidity should be before opening sterile supplies for a surgical procedure. Staff #S279 stated, "68-72 degrees for the temperature and I'm not sure about the humidity."</p> <p>An interview with Staff #S205 was conducted on 9/20/2015 after 9:30 AM. Staff #S205 was asked if the temperature and humidity was logged on a temperature log daily for each OR. Staff #S205 replied, "Engineering monitors the temp and humidity for the OR's, so we do not log them daily. The staff is supposed to look at the temperature and humidity in the room and call the engineering department if it needs to be adjusted before they open the case." Staff #S205 was asked which national guidelines were being followed for the department. Staff #S205 stated, "We follow AORN Guidelines."</p> <p>A Review of the documents titled, ---Hosp 2. "OPER. RM. Temp. &amp; Humidity Log sheet" dated 8/22/2019 through 9/20/2019 revealed the following:</p> <p>3rd Floor Operating Rooms</p>	A 940			



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A 940	Continued From page 368  OR #1 - The temperature was documented out of range 28 of 30 days.  OR #2 - The temperature was documented out of range 24 of 30 days.  OR #3 - The temperature was documented out of range 30 of 30 days.  OR #4 - The temperature was documented out of range 30 of 30 days.  OR #5 - The temperature was documented out of range 30 of 30 days.  OR #6 - The temperature was documented out of range 30 of 30 days.  2nd Floor Operating Rooms  OR #11 - The temperature was documented out of range 30 of 30 days.  OR #12 - The temperature was documented out of range 30 of 30 days.  OR #13 - The temperature was documented out of range 2 of 30 days.  OR #14 - The temperature was documented out of range 29 of 30 days.  An interview was conducted with Staff #S457 and #S229 on 9/20/2019 at 11:00 AM. Staff #S457 was asked how he monitored the rooms for the correct temperature and humidity ranges. Staff	A 940			

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A 940	<p>Continued From page 369</p> <p>#S457 replied, "Every morning I come in, there is a report for each OR and the Sterile Processing Department (SPD). I review the report and see if the ranges are ok at that time. The rest of the day the system will alarm if the temperature or humidity is out of range." Staff #S457 was asked if he notified the OR if the temperature or humidity was out of range. Staff #S457 said, "I call #64511 if the ranges are not correct and I adjust the temperature." Staff #S457 asked if the adjustments or the follow up temperature and humidity were documented anywhere. Staff #S457 said, "The only time we document the adjustments is when someone from the OR calls and asks us to adjust the temperature." Staff #S457 reported that only the plant operations team were able to adjust the temperature and humidity and not the engineers.</p> <p>Staff #S229 agreed with the answers given by Staff #457.</p> <p>A review of the document titled, "Operating Room Temperature Adjustments" revealed only three adjustments had been documented between 8/22/2019 and 9/20/2019. Further review revealed, there was no 15 min follow up documented.</p> <p>A review of the AORN Perioperative Standards and Recommended Practices,</p> <p>" ...Temperature should be maintained between 68 degrees F to 75 degrees Fahrenheit (20 degrees to 23 C) within the operating room suite. General work areas in sterile processing should be maintained between 68 degrees to 73 degrees</p>	A 940			

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A 940	<p>Continued From page 370</p> <p>F.</p> <p>Relative humidity should be maintained between 20% and 60% within the perioperative suite, including operating rooms, recovery area, cardiac catheterization rooms, endoscopy rooms, instrument processing areas, and sterilizing areas and should be maintained below 60% in sterile storage areas.</p> <p>Low humidity increases the risk of electro static charges, which pose a fire hazard in an oxygen-enriched environment or when flammable agents are in use and increases the potential for dust. High humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed.</p> <p>Humidity should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system.</p> <p>Temperature should be monitored and recorded daily using a log format or documentation provided by the HVAC (heating, ventilation, and air conditioning) system..."</p> <p>Staff #S229 confirmed the above findings.</p> <p>Pre-operative Holding area 3rd Floor</p> <p>During a tour on 9/16/2019 after 10:30 AM accompanied by Staff #S204 and #S205 the following observations were made:</p> <p>A purple multi-drawer cart that stored supplies for patient use prior to surgery was noted to have 2</p>	A 940			

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A 940	<p>Continued From page 371</p> <p>yellow top blood tubes that expired on 7/10/2019 and 5 red top blood tubes that expired 7/31/2019. These tubes are used to draw a patient's blood prior to surgery. Staff #S205 was asked who stocked and managed the supplies on the cart. Staff #S205 said, "The anesthesia techs stock the cart."</p> <p>Next to the purple cart is a small room/cove that holds patient belongings, some office supplies, an ice machine, cups, and straws for patient use. The top of the counter above the drawer labeled "cups" was broken and visibly soiled with dirt and dust. In the drawer labeled "cups" were cups, straws, and small pill cups. The inside of the drawer was soiled with a dried liquid, dirt, dust, and debris. The lower cabinets labeled "chlorhexidine wipes and Bio Bags" was missing the locking mechanism leaving a large hole in the cabinet door. There were chips in the door face exposing the porous wood surface underneath. Porous wood surfaces cannot be properly sanitized. In the pre-op bay directly across the room was a clean patient stretcher ready to receive a new patient. There was a hole in the sheet that was on the stretcher.</p> <p>Post Anesthesia Care Unit 3rd Floor</p> <p>A tour of the PACU dept was conducted on 9/16/2019 with Staff #S200 and #S204 after 1:00 PM. The following observations were made:</p> <p>The door frame to the isolation room was chipped and missing paint exposing the metal surface. The crash cart (a cart storing emergency medications and supplies used during emergencies) was opened by Staff #S200. The</p>	A 940			

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A 940	<p>Continued From page 372</p> <p>3rd drawer was stocked with supplies for the airway. There were Miller and Mac blades (laryngoscope blades used to intubate a patient) that were open. The blades are required to be high level disinfected and stored in a closed pouch until ready for use. The sealed pouch was found to be opened and exposing the Miller and Mac blades to dirt, dust, and contaminated human hands, increasing the risk of hospital acquired infections. In the 4th drawer a sterile instrument tray for an emergency chest tube placement, was found with a non-sterile #11 and #15 scalpel (a disposable knife blade) slid into the sterile wrap. This put the sterile instrument tray at risk of contamination.</p> <p>Staff #S200 confirmed the above findings.</p> <p>Sterile Corridor 3rd Floor</p> <p>The wall above the automated storage for supplies used in the operating rooms was missing paint exposing the sheetrock underneath. A hole and missing paint in the corner next to exit door was noted. Four standing stools, used in the operating rooms were stacked against the wall beneath the fogarty catheters (catheters used to remove a blood clot within the vascular system). The stools were noted to be rusty with dried adhesive on the surface. Rust cannot be properly cleaned or sanitized. On the wall above the stools were fogarty catheters hanging from a rack that had pulled away from the sheetrock and left a hole in the wall exposing the sheetrock. The exposed sheetrock cannot be sanitized and left an opening for small insects to enter the sterile core.</p>	A 940			

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A 940	<p>Continued From page 373</p> <p>Staff #S205 confirmed the above findings.</p> <p>Storage Room 4th Floor</p> <p>An observation tour was conducted on 9/26/2019 at 9:30 AM with Staff #S205. The following was observed in the Storage Room on the 4th floor next to the Sterile Processing Department:</p> <p>Multiple shelves were noted without a protective barrier on the bottom shelf. This increased the risk of cross contamination of cleaning supplies to splash onto the sterile items stored on the bottom shelf.</p> <p>A multi-tier shelf that had a solid metal bottom, storing patient supplies, was noted to be heavily covered with dirt and dust. The floor was covered with dirt, dust, and debris. The wall at the back of the room was visualized having a dark brown stain going horizontally down the wall. Staff #S205 was asked what the brown stain was. Staff #S205 stated, "It looks like the same color at the ceiling where they repaired some of the cracks at the top and it probably just got on the wall. I will make sure they repaint in here." Corrugated boxes were noted to be stored on a few shelves in the room.</p> <p>A review of the AORN (Association of perioperative Registered Nurses) 2019 Perioperative Standards and Recommended Practices, Guidelines for Sterilization, revealed the following:</p> <p>"...Recommendation IV.c. Supplies and equipment should be removed from external</p>	A 940			

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A 940	<p>Continued From page 374</p> <p>shipping containers and open-edged corrugated cardboard boxes before transfer to the sterile storage area or point of use.</p> <p>External shipping containers and open-edged cardboard boxes may collect dust, debris, and insects during shipment and may carry contaminants into the surgical suite ..."</p> <p>Staff #S205 confirmed the above findings.</p> <p>HOSPITAL #2</p> <p>During a tour of the Post Anesthesia Care Unit at hospital #2 on 09/16/19 beginning at 1:30 p.m. accompanied by Staff #205, Staff #204, and Staff #200, observations revealed the following:</p> <ol style="list-style-type: none"> <li>1. An ice machine used for patients was sitting on a countertop with a crack to the back right side such that the countertop could not be properly cleaned.</li> <li>2. The pink drawer of a Broselow Cart contained a Magill forceps in a discolored peel pouch, a laryngoscope blade with tears in the peel pouch, and an unwrapped oral airway. The white drawer contained a #3 Mac laryngoscope blade with tears in the peel pouch. The green drawer contained an unwrapped oral airway.</li> </ol> <p>The above findings were confirmed during an interview of Staff #200 in the PACU at hospital #2 on 09/16/19 at 2:00 p.m.</p> <p>During a tour of the Gastrointestinal (GI) Lab at hospital #2 on 09/17/19 beginning at 10:35 a.m. accompanied by Staff #205, Staff #204, and Staff</p>	A 940			

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A 940	<p>Continued From page 375</p> <p># 202, observations revealed drawer 4 of the crash cart contained a wrapped crash cart kit with a disposable #11 scalpel and #15 scalpel tucked between the layers of wrapping such that sterility of the wrapped instruments could not be assured.</p> <p>The above findings were confirmed with Staff #205 in an interview in front of the GI crash cart at hospital #2 on 09/17/19 at 11:10 a.m.</p> <p>During an inspection of room 2 in the cardiology department at hospital #2 accompanied by Staff #213 on 09/17/19 at 3:13 p.m., observation revealed that the TEE was stored in a horizontal position in a hard plastic transparent transport case on the top shelf in a cabinet and not in a vertical hanging position. Staff #213 could not provide documentation that temperature and humidity was being monitored.</p> <p>The above findings were confirmed with Staff #213 at hospital #2 on 09/17/19 at 3:13 p.m. in an interview in room 2 in cardiology where the TEE was stored.</p> <p>During a tour of the Sterile Core at hospital #2 on 09/18/18 beginning at 10:45 a.m. accompanied by Staff #204, Staff #215 and Staff #216, observation revealed the following:</p> <ol style="list-style-type: none"> <li>1. A paper sack was stored on top of sterile supplies and instruments.</li> <li>2. Paper sacks were stored on top of shelves above sterile supplies.</li> <li>3. Folded paper sacks and 2 staplers were</li> </ol>	A 940			



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A 940	<p>Continued From page 376 stored next to sterile supplies.</p> <p>4. Peel pouches contained instruments with unprotected tips such that the integrity of the packaging could be breached including a pair of ophthalmic scissors, a forceps retractor, scissors, an eye retractor, a towel clip and a pair of Potts scissors.</p> <p>5. Instruments in peel pouches with holes including two orthoscopic graspers, Stammberg forceps, and an eye elevator.</p> <p>6. Instruments in discolored peel pouches including a Stammberg forceps, a pair of Karl Storz scissors, an instrument labeled OPC Procure Arthroscopy Scope Set and an unlabeled instrument.</p> <p>7. Hinged instruments packaged in peel pouches in a closed position including a mosquito forceps, a lahey clamp, a sponge forceps and 2 tenaculums.</p> <p>The above findings were confirmed with Staff #215 and Staff #216 at hospital #2 in an interview in the Sterile Core on 09/18/19 at 11:55 a.m.</p> <p>During a tour of the Sterile Processing Department at hospital #2 on 09/19/19 at 2:30 p.m. accompanied by Staff #217, observation revealed chipped tiles in front of the two steam sterilizers confirmed by Staff #217 in an interview at the time of the observation.</p> <p>During a tour of the operating suite on the 3rd floor at hospital #2 on 09/23/19 at 11:10 a.m.</p>	A 940			

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A 940	<p>Continued From page 377</p> <p>inspection of the intubation cart in the Anesthesia Storage Room and in the presence of Staff #205 and Staff #458, observation revealed 2 peel pouches that each contained a bougie. According to Staff #458, the bougies are reusable. The peel pouches did not contain any reprocessing information such that it could not be determined that the bougies had been disinfected/sterilized between patients.</p> <p>In an interview on 09/23/19 at 11:10 a.m. in the Anesthesia Storage Room, Staff #458 at hospital #2 confirmed the above findings.</p> <p>During an inspection of the Pyxis cabinet for the storage of medications in the sterile corridor of the operating suite at hospital #2 on 09/23/19 at 11:28 a.m. in the presence of Staff #205, observation revealed dried drippage on the inside and outside of the clear plexi-glass door of the bottom shelf and areas of black debris to the lower shelf that could be removed from both areas by wiping them with an Oxivir wipe.</p> <p>In an interview on 09/23/19 at 11:28 a.m. in front of the Pyxis cabinet in the sterile corridor of the operating suite at hospital #2, Staff #205 confirmed the above findings.</p> <p>The hospital policy no. 1303 entitled, "Pre-cleaning, Sterilization, High and Low Level Disinfection, and Storage of Processed Patient Care Devices," with an effective date of "12/16," was reviewed on 09/17/19 at 9:10 a.m. in a conference room at hospital #2 and stated the following in part:</p>	A 940			

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A 940	Continued From page 378  PURPOSE: To prevent the transmission of infections associated with the use of reusable patient care devices, and to provide infection control guidelines for pre-cleaning, sterilization, high or low level disinfection of such items.  IV: Packaging Supplies for Sterilization  J. Packaging must:  5. Be a reliable barrier to dust particles that carry microorganisms;  8. Resist tearing and puncturing under ordinary conditions of use.  9. Protect the package contents from physical damage  Appendix C Steam Sterilization  II. 3. ...All packages should be visually inspected for tears and wetness with dropped items returned to Decontamination for reprocessing.  4. Items that are torn, damaged or wet should be considered contaminated and not used.  Appendix M  Storage and Transportation of Patient Care Medical Devices and Other Patient Care Items After Sterilization or High-Level Disinfection  A. Scopes should be hung upright in a covered	A 940			

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A 940	Continued From page 379 cabinet for storage after processing.  Appendix N Sterile Items  A. Sterile items should be stored in a manner that will reduce the potential for contamination:  1. Room temperature should be approximately 24°C (75°F);  2. The room(s) should have at least four (4) air exchanges per hour; and  3. Humidity should be controlled so that it does not exceed seventy percent (70%).  B. Traffic should be controlled and access limited to those individuals who have been trained in the proper handling of sterile items.  C. Sterile items should be stored in a manner that will permit adequate air circulation and permit thorough cleaning of the storage space. Items should be stored at least 8 to 10 inches above the floor ...  D. Items should be positioned to prevent crushing, compression, bending or puncture.  F. Sterile supplies should not be stored on floors, window sills or in areas other than designated shelving, counters, or carts.  G. Outside shipping containers, (corrugated cardboard cartons) should not be used as containers in sterile storage areas.	A 940			

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A 940	<p>Continued From page 380</p> <p>Review of an e-mail dated 09/18/19 at 3:30 p.m. from Staff #229 regarding a request for 30 days humidifier monitoring Engineering logs for TEE in Cardiology clinic room RM2-NO32008C stated the following, "Unfortunately this is not a room that we are capable of monitoring remotely. We do not have any records for temp or humidity."</p> <p>The hospital policy entitled, "Transesophageal Echo Probe Disinfecting Pre-Cleaning Guidelines," with an effective date of "10/2006," and a last revised date "07/19," was reviewed on 09/26/19 at 2:50 p.m. in a conference room at hospital #2 and stated the following in part:</p> <p>Procedure:</p> <p>11. Probes will stay in sterile processing probe cabinet until ready to be picked up and used for TEE procedure.</p> <p>12. All clean Transesophageal Echo probes will be picked up in clear transport case with green tags sealing the case and also a green tag attached to the probe wire.</p> <p>13. TEE probe log is to be checked daily. Probes should not hang in the sterile processing probe cabinet for more than 14 days. Any probes that have not been used or cleaned in more than 14 days will be taken out to be pre-cleaned and taken to sterile processing for complete cleaning again.</p> <p>The "GE Healthcare Technical Publications TEE probes User Manual Rev. 07," was reviewed on 09/26/19 at 2:55 p.m. in a conference room at</p>	A 940			

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A 940	Continued From page 381 hospital #2 and stated the following in part, "Storage 3. The probe should be stored in a vertical orientation on a Storage rack. The handle should be stored so that the flexible shaft is pointing down and is hanging freely ...Recommended storage temperature range: Between 0°C and +45°C.	A 940			
A 955	INFORMED CONSENT CFR(s): 482.51(b)(2)  A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.  This STANDARD is not met as evidenced by: HOSPITAL #1  Based on observation, record review, and interview, the facility failed to ensure that the patient was provided all information necessary to make an informed decision on their care in 9 (Patient #'s 41, 42, 44, 203, 204, 205, 206, 207, and 208) of 9 surgical charts reviewed. Also, the facility failed to ensure that an informed telephone consent had two witnesses as required per facility policy for 1 (#205) of 1 surgical patients in 2 of 2 hospitals. Hospital #s 1 and 2  Hospital 1  (A) Based on observation, record review, and interview, the facility failed to ensure that the patient was provided all information necessary to make an informed decision on their care in 4 (Patient #398, #399, #400, and #401) of 4 surgical charts reviewed.  (B) the facility failed to ensure a properly	A 955			

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A 955	<p>Continued From page 382</p> <p>executed informed consent was obtained prior to Patient # 404 undergoing a bronchoscopy under moderate sedation.</p> <p>(C) hospital #2 failed to ensure a properly executed consent for 4 (Patient #233, #234, #235, and #237) of 6 patients whose medical records were reviewed because the surgeon who performed the surgery was not listed on the operative consent and the hospital failed to follow it's own policy on informed consents.</p> <p>Findings:</p> <p>Hospital 1</p> <p>The facility failed to:</p> <p>A. ensure that all practitioners who were performing surgery were listed on the informed consent. There was no way to ensure the patient was fully informed what practitioner would be performing their surgery.</p> <p>B. ensure that the informed consent was dated and timed by the patient and witness. There was no way to ensure that the informed consent was done prior to the start of the procedure.</p> <p>C. ensure that an informed telephone consent had two witnesses as required per facility policy for surgical patients.</p> <p>An interview with Staff #S309 on September 25, 2019, after 9:00 a.m. revealed the following:</p> <p>Staff #S309 stated, "On the informed consent it</p>	A 955			

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A 955	<p>Continued From page 383</p> <p>states the patient requests my physician, and such associates, technical assistants and other health care providers as they deem necessary, to treat my condition." Staff #S309 stated, "The facility does not list all residents and fellows. This above statement covers anyone that performs the surgery. Staff #S309 stated, "The physicians know and acknowledge they are fully responsible for any resident/fellow that works under them." Staff #S309 was asked if the patient was given information prior to the surgery regarding who would be performing their surgery. Staff #S309 stated, "Well that it is the facility's expectation."</p> <p>Review of the facility policy and procedure titled, "Consent for Medical Treatment and Identification of a Surrogate Decision Maker" with an effective date of 12/2006 revealed the following:</p> <p>"B. Informed Consent</p> <p>3.a. The form shall be signed and dated by the patient or the patient's LAR, a competent witness, and the healthcare provider administering the treatment or performing the procedure...</p> <p>4. The Informed Consent form shall contain the name of the responsible Healthcare provider who is performing the procedure or administering the medical treatment ..."</p> <p>Hospital #1</p> <p>C. Telephone Consent</p> <p>Patient #205 was a 50-year-old male admitted to hospital on 8/22/2019 with history of roux-en-y gastric bypass and depression. Also, has history</p>	A 955			



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A 955	<p>Continued From page 384</p> <p>of encephalopathy, anorexia, and significant weight loss. Patient was scheduled for surgery on 9/18/2019 for open versus laparoscopic gastrotomy tube and possible jejunostomy tube. The patient was evaluated by the primary team and psychiatry that the patient lacks the capacity to decline Peg placement. The family was involved in the decision making.</p> <p>Review of the facility document titled, "Disclosure and Consent, Medical and Surgical Procedures" revealed the consent was a telephone consent given by the mother of the patient. The consent signature was only witnessed by one staff registered nurse. There was only one witness and the signature of the witness had no time or date on the consent.</p> <p>The surgical procedure was performed on 9/23/2019.</p> <p>A review of the facility's policy titled, "CONSENT FOR MEDICAL TREATMENT AND IDENTIFICATION OF A SURROGATE DECISION-MAKER" revealed the following:</p> <p>"Purpose: To provide guidelines for obtaining and documenting consent for nonemergency medical care and treatment and surgical and diagnostic procedures, including the identification of a surrogate decision-maker, when appropriate.</p> <p>H. INFORMED CONSENT: Permission given by a patient or patient's legally authorized representative to perform a medical treatment or surgical procedure after the patient has been advised of the risks or hazards that could influence a reasonable person in deciding</p>	A 955			

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A 955	<p>Continued From page 385</p> <p>whether or not to give permission. In order for the patient to make an informed decision about whether to give his or her permission, the patient needs information about the treatment or procedure, the Practitioner(s) or Healthcare Provider(s) who will actually provide the treatment or perform the procedure, and the risks and hazards associated with it that could influence a reasonable person to make a decision to give or withhold consent."</p> <p>An interview with Staff #S429 on 9/23/2019 at 2:30 PM confirmed there was only one signature on the telephone consent form. The facility failed to follow its own Disclosure and Consent policy.</p> <p>Hospital #2</p> <p>A review of Patient #398's medical record revealed that all practitioners who performed the procedure were not listed on the informed consent. There was no way to ensure the patient was fully informed what practitioner would be performing their surgery. During observation on 9/17/2019 of the procedure, it was noted the provider on the informed consent was not the provider who performed the procedure.</p> <p>A review of Patient #399's medical record revealed that all practitioners who performed the surgical procedure were not listed on the informed consent. There was no way to ensure the patient was fully informed what practitioner would be performing their surgery. A post procedure note was written by a provider that was not listed on the consent. The primary surgeon listed additional staff assisting in the surgical procedure on the postoperative note.</p>	A 955			

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A 955	<p>Continued From page 386</p> <p>A review of Patient #400's medical record revealed that all practitioners who performed the surgical procedure were not listed on the informed consent. There was no way to ensure the patient was fully informed what practitioner would be performing their surgery. The postoperative note was written and revealed an additional Resident MD performed much of the surgical procedure but was not listed on the informed consent.</p> <p>A review of Patient #401's medical record revealed that all practitioners who performed the surgical procedure were not listed on the informed consent. There was no way to ensure the patient was fully informed what practitioner would be performing their surgery. A review of the postoperative note was written by Resident MD that performed/assisted with the surgical procedure. The Resident MD was not listed on the informed consent.</p> <p>A review of the facility policy and procedure titled, "Consent for Medical Treatment and Identification of a Surrogate Decision Maker" with an effective date of 12/2006 revealed the following:</p> <p>" ...B. Informed Consent</p> <p>3.a. The form shall be signed and dated by the patient or the patient's LAR, a competent witness, and the healthcare provider administering the treatment or performing the procedure...</p> <p>4. The Informed Consent form shall contain the</p>	A 955		

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A 955	<p>Continued From page 387</p> <p>name of the responsible Healthcare provider who is performing the procedure or administering the medical treatment ..."</p> <p>An interview was conducted with Staff #S202 on 9/17/2019 after 10:00 AM. Staff #S202 was asked if they list the residents on the informed consents. Staff #S202 replied, "Only fellows can do procedures in the GI Lab. We do not list them on the consent, only the attending is on the consent." Staff #S202 was asked if the patient was informed that someone other than the attending would be performing the procedure. Staff #S202 stated, "The attending or the fellow does the consent and I'm sure the patient is aware of that."</p> <p>Staff #S202 confirmed the above findings.</p> <p>Hospital #2</p> <p>During a medical record review for Patient #233, #234, #235, #236, #237, and #238 with Staff #S205 at hospital #2 on 09/26/19 at 10:10 a.m. in an administrative office the findings revealed the following:</p> <p>The faculty surgeon listed on the operative consent signed by the patient was not the surgeon identified in the operative report who actually performed the surgery for patient #233, #234, #235, and #237.</p> <ol style="list-style-type: none"> <li>1. Patient #233 - the resident was listed as the surgeon on the op note.</li> <li>2. Patient #234 - the resident completed the op note that stated, "I began the procedure on the right side" and "Dr ...was present and scrubbed</li> </ol>	A 955			

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A 955	<p>Continued From page 388 for the entirety of the procedure" which was the name of the faculty surgeon on the consent.</p> <p>3. Patient #235 - the resident was listed as the surgeon on the op note.</p> <p>4. Patient #237 - the teaching physician that noted he performed the procedure with the resident was not the faculty surgeon listed on the operative consent.</p> <p>The above findings were confirmed with Staff #S205 in an interview on 09/26/19 at the time of the medical record reviews at hospital #2. In addition, Staff #S205 stated, "We can't list multiple surgeons. It has to be a single name and has to be a faculty surgeon. We don't list the residents because they do the consent in the clinic before the surgery date and the resident may change because they rotate. The resident may have moved on to another hospital."</p> <p>The hospital policy no. 4215 entitled, "Consent for Medical Treatment and Identification of a Surrogate Decision Maker," with an effective date of "12/2006," was reviewed on 09/26/19 at 11:45 p.m. with Staff #S205 in an administrative office at hospital #2 and stated the following in part:</p> <p>IV. OBTAINING AND DOCUMENTING CONSENT:</p> <p>B. Informed Consent</p> <p>3. The patient's medical record shall contain a properly executed Informed Consent form, ...Disclosure and Consent for Medical and Surgical Procedures, ...or Disclosure and Consent for Dental and Surgical Procedures</p>	A 955			

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A 955	<p>Continued From page 389</p> <p>...prior to conducting any procedure or other type of treatment that requires Informed Consent, except in emergencies ...</p> <p>4. The Informed Consent form shall contain the name of the responsible Healthcare Provider(s) who is performing the procedure or administering the medical treatment: ...</p> <p>Hospital 2</p> <p>Review of facility's policy titled " Consent for Medical Treatments and Identification of a Surrogate Decision-Maker,"dated 12/2006, showed "... IV. B 3. The patient's medical record shall contain a properly executed Informed Consent...prior to conducting any procedure or other type of treatment that requires informed consent except in emergencies...B.4. the Informed Consent form shall contain the name of the responsible Healthcare provider(s) who is performing the procedure..."</p> <p>Observation on 09-24-19 at 9:15 A.M., showed Patient # 404 undergoing a bronchoscopy procedure. [*A bronchoscopy is a procedure that allows a doctor to examine the inside of the lungs, including the bronchi, which are the main pathways into the lungs. During a bronchoscopy, a doctor inserts a thin tube containing a light and camera into the lungs through the nose or mouth.]</p> <p>Staff #S731, the attending MD , was in the room during the procedure, however, Staff #S732, the fellow, actually performed the entire procedure.</p> <p>Review of the "Disclosure &amp; Consent For Medical</p>	A 955			

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A 955	Continued From page 390 & Surgical Procedures", listed the following procedures: bronchoscopy, airway exam, endobronchial biopsy, moderate sedation, aragon plasma coagulation, and bronchioalveolar lavage."  The physician listed as performing the procedure was Staff #S731, the attending physician. The fellow, Staff# S732 who actually performed the bronchoscopy was not listed anywhere on the consent form. This was verified by Staff RN #S748 .	A 955			
A 956	REQUIRED OPERATING ROOM EQUIPMENT CFR(s): 482.51(b)(3)  The following equipment must be available to the operating room suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.  This STANDARD is not met as evidenced by: Based on observation and staff interviews, the facility failed to monitor and implement a sanitary environment. Six (6) surgical instruments were observed rusty in plastic pouches available for patient use.  Findings:  During a tour on 9/17/19 at hospital #2 nuclear medicine department accompanied by staff #S90 and #S238, a pair of rusty hemostats in plastic pouch were observed in the emergency cart available for patient use. Staff #S238 agreed with the findings.  During a tour 9/19/19 at 11:40 am at Outpatient clinic # 6 in central supply, five (5) rusty surgical	A 956			

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A 956	Continued From page 391 instruments were observed in plastic pouches available for patient use.	A 956			
A1002	<p>The findings were confirmed by staff #S258 during the tour.</p> <p><b>DELIVERY OF ANESTHESIA SERVICES</b> CFR(s): 482.52(b)</p> <p>Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient:</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to ensure that policies and procedures that included pre and post anesthesia evaluation responsibilities were developed and implemented.</p> <p>This deficient practice had the likelihood to cause harm in all patients receiving anesthesia services at the facility in 2 of 2 hospital anesthesia services reviewed Hospital 1 and 2.</p> <p>Findings:</p> <p>Hospital (1)</p> <p>A request was made on September 16, 2019, after entrance for the anesthesia policy and procedure table of contents. On September 23, 2019, review of the table of contents for anesthesia revealed three policies; Moderate Sedation, Universal protocol, Consent for</p>	A1002			



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A1002	<p>Continued From page 392</p> <p>Treatment and Surrogate Decision Maker. There was no policy specific to anesthesia that included pre and post anesthesia evaluation listed.</p> <p>An interview with Staff #S309 on September 25, 2019, after 9:00 a.m. confirmed that the facility did not have any anesthesia policies and procedures.</p> <p>Review of the facility document titled, "-- Health System Medical Staff Rules &amp; Regulations" revealed the following:</p> <p>"H. Anesthesia A Pre-anesthesia and post-anesthesia note must be documented for each patient anesthesia."</p> <p>There were no criteria included on who could perform the evaluations, what information should be included in the evaluations, and when if any time frames on when the evaluations should be performed. Hospital #2</p> <p>An interview was conducted with Staff #S671 on 9/23/2019 after 10:00 AM. Staff #S671 was asked to provide the anesthesia policies and procedures regarding pre and post-op evaluations by anesthesia. Staff #S671 said there are no specific anesthesia policies they will be addressed in the --- Health System Medical Staff Rules &amp; Regulations.</p> <p>A review of the document titled, "STATEMENT ON ANESTHESIA SERVICES AT Hospital 2 " was as follows:</p>	A1002			

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A1002	Continued From page 393 " ...The anesthesia service at Hospital 2 will follow the American Society of Anesthesiology guidelines, the ---- Health Bylaws and Rules and Regulations, the Harris Health credentialing requirements for the administration of anesthesia, and the CMS Conditions of Participation ..."  No documentation was perceived or provided by Staff #S671 regarding the Governing Body's approval of the anesthesia services statement or approval of the guidelines to ensure patient safety.  Review of the facility document titled, "---Health System Medical Staff Rules & Regulations" revealed the following: " ...H. Anesthesia A Pre-anesthesia and post-anesthesia note must be documented for each patient anesthesia."  There was no criteria including who could perform the evaluations, what information should be included in the evaluations, and when if any time frames on when the evaluations should be performed. Staff #S671 confirmed the above findings.	A1002			
A1081	STANDARD TAG FOR OUTPATIENT SERVICES CFR(s): 482.54  Standard-level Tag for  §482.54 Condition of Participation: Outpatient Services  If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of	A1081			

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A1081	<p>Continued From page 394 practice.</p> <p>This STANDARD is not met as evidenced by: Based on observations, interviews, and record review, the outpatient services provided by the facility failed to meet the needs of the patients in accordance with acceptable standards of practice regarding the sterilization of instruments ( citing outpatient clinics 7, 8, and 9).</p> <p>Findings:</p> <p>Facility policy No. 1303 entitled "PRE-CLEANING, STERILIZATION, HIGH AND LOW LEVEL DISINFECTION, AND STORAGE OF PROCESSED PATIENT CARE DEVICES" stated in part,</p> <p>"III. CLEANING AND DECONTAMINATION: ...</p> <p>D. Instruments must be disassembled and with hinges opened and sprayed with enzymatic solution ...</p> <p>APPENDIX H TABLE-TOP STEAM STERILIZERS I. GENERAL CONSIDERATIONS: ...</p> <p>C. Table-top steam sterilizers must have recording devices to monitor and provide a read out for time, temperature and pressures during the time that a sterilizer is in operation, i.e. sterilizing a load ...</p> <p>G. Temperature 75°F.</p> <p>H. Humidity thirty percent (30%)- sixty percent (60%) ...</p>	A1081			

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A1081	Continued From page 395  III. BIOLOGICAL INDICATORS (BI): ...  G. After the sterilizer cycle, incubate the BI test and control vials (Note: the control vial must be from the same lot # as the processed BI). Label the control for the BI with a "C" and date. Read and record the results.  H. Record the results for the BI ...  L. Load documentation: label each item or pack with a "lot control identifier" to be used in the event of a recall, to trace problems such as wet packs to their source and to facilitate proper stock rotation:  1. The "lot control identifier" should include the sterilizer number, the cycle number and the date of sterilization;  2. Records on cycle parameters must be kept for each sterilization cycle;  3. Lot number;  4. Contents of load;  5. Exposure time and temperature if not on a recording chart;  6. Operator signature;  7. Results of BI testing;  8. Results of CI and the BI challenge test pack; ...  APPENDIX I	A1081			

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A1081	<p>Continued From page 396</p> <p><b>STERILIZATION PROCESS MONITORING</b></p> <p><b>I. GENERAL REQUIREMENTS: ...</b></p> <p>A. Every load should:</p> <p>1. Be physically-monitored for time, temperature, and pressure. Before items are removed from the sterilizer, check printout to verify that all cycle parameters were met and sign the printout; ...</p> <p><b>VI. LOAD DOCUMENTATION:</b></p> <p>For each sterilization cycle, the following information should be recorded and maintained: ...</p> <p>B. Contents of load;</p> <p>C. Exposure time and temperature if not on a recording chart;</p> <p>D. Operator signature;</p> <p>E. Results of BI testing, if applicable;</p> <p>F. Results of CI and the BI challenge test pack; ...</p> <p><b>APPENDIX K</b> <b>GUIDELINES FOR HIGH-LEVEL DISINFECTION</b> ...</p> <p>G. Prior to placement of instruments into the disinfectant solution, they must be thoroughly cleaned with a suitable detergent by brushing the surfaces to remove all blood, body fluids, tissue and any other foreign matter. Hinged instruments must be opened to permit thorough removal of all organic material. Lumens in instruments must be</p>	A1081			

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A1081	<p>Continued From page 397 thoroughly brushed and irrigated until clean ...</p> <p><b>APPENDIX N STERILE ITEMS</b></p> <p>Sterile items should be stored in a manner that will reduce the potential for contamination:</p> <ol style="list-style-type: none"> <li>1. Room temperature should be approximately 24°C (75°F);</li> <li>2. The room(s) should have at least four (4) air exchanges per hour; and</li> <li>3. Humidity should be controlled so that it does not exceed seventy percent (70%)."</li> </ol> <p>During tours of the outpatient sites, the following observations were made regarding sterilization.</p> <p>On 09/18/19, Outpatient clinic #6 same day clinic dental sterilization area was toured and the following findings were noted:</p> <p>* It was observed that 13 instruments with a locking mechanism were with the locking mechanism in a closed and clamped position. The locking mechanism is a series of interlocking teeth on each handle that clamps and holds the instrument handles in place with tension. When instruments are closed, the sterilizing agent cannot penetrate all surfaces to ensure complete sterilization of all surfaces of the instruments.</p> <p>The above was confirmed in interview with staff member S647, who performs instrument sterilization at this location.</p>	A1081			

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A1081	Continued From page 398  Per the Centers for Disease Control and Prevention (CDC) article, GUIDELINE FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES, 2008, by William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), found at: <a href="http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf">http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf</a> , states on page 74 that hinged instruments and instruments that close should be opened during the process of sterilization.  During the tour of outpatient clinic # 6 same day clinic dental sterilization area on 09/18/19, it was noted that the sterilization log did not contain the temperature, time, or duration of the sterilization process. The logs for September 2019 only included the items sterilized, machine used, and the operator identification.  In an interview, staff #S647 stated that they did not have the ability to print out the record of time, temperature, and duration from the autoclave machine. The staff member verbalized the machine maintained a temperature of over 270 degrees Fahrenheit for at least 30 minutes, but there was no documentation to reflect that. Per policy and standard practice, the temperature, time, and duration need to be documented when sterilizing instruments.  On 09/24/19, the Outpatient health center #7 sterilization area was toured and the following	A1081			

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A1081	<p>Continued From page 399 finding was noted:</p> <p>* Review of the biological indicator log for 2019 revealed that the test results of the control vial were not documented consistently. The following dates did not have results of the control vial documented: from 04/07/19 through 05/08/19, and 08/08/19 through 08/29/19.</p> <p>In an interview, staff member #S651 confirmed that the control vial results of the biological indicators were not consistently documented. Staff member #S651 performs instrument sterilization at this location.</p> <p>On 09/25/19, the outpatient Home Health Center #9 dental sterilization area was toured and the following finding was noted:</p> <p>* According to the temperature and humidity log, the humidity in the room had been out of range throughout September. The acceptable range according to the form was 30%-60%. The range was too high on the following dates: 9/4 - 63%, 9/6 - 62%, 9/9 - 63%, 9/10 - 62%, 9/11- 63%, 9/12- 65%, 9/13 - 61%, 9/17 - 62%, 9/18 - 62%, and 9/24 - 61%.</p> <p>In an interview, staff member #S662, who performs instrument sterilization at this location, stated that the out of range humidity readings had not been reported to maintenance or adjusted. According to facility policy, the humidity in the sterilization area is not to exceed 70%, however, the form used at his location indicated the humidity should be maintained under 60%. Staff member S661 verified that the humidity over 60%</p>	A1081			



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A1081	Continued From page 400 should have reported to maintenance and a work order entered to adjust the humidity in the room.  Based on the above findings, the facility failed to ensure that sterilization of instruments at various outpatient locations was consistent with acceptable standards of practice and facility policy as evidence by failing to appropriately log the temperature, time, and exposure duration of instruments in the sterilizer, failing to document the required test control vial results for biological indicators, and failing to maintain appropriate humidity in the sterilization area. The above findings were confirmed on 09/26/19 in an interview with staff members #S613 and #S631.	A1081			
A1123	REHABILITATION SERVICES CFR(s): 482.56  If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.  This CONDITION is not met as evidenced by: Based on record review and interviews, the facility failed to:  a. ensure adequate numbers of physical therapy (PT) staff available to ensure timely evaluations, safe, and efficient treatment, in 3 (432, 433, and 435) of 4 (432 - 435) patient charts reviewed.  b. ensure the rehabilitation services be integrated into the hospital-wide Quality Assessment Performance Improvement (QAPI) program.	A1123			

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A1123	<p>Continued From page 401</p> <p>c. ensure policy and procedures were properly updated and reviewed.</p> <p>Findings:</p> <p>Hospital #2</p> <p>Patient #432</p> <p>Review of Patient #432's chart revealed, she was a 3-month-old female. Patient #432 was born on 6/12/19 and a patient at the NICU ( neonatal intensive care unit). Review of the physician's orders revealed a physical therapy evaluation was ordered on 6/13/19 at 8:22 am.</p> <p>Review of Staff #S734 note dated 6/14/19 at 7:55 AM stated, "PT consult received and reviewed. Chart reviewed. Pt currently intubated. Will await improved respiratory status (at least on CPAP) prior to performing PT evaluation. Will continue to monitor weekly. Please call with any questions. Thank you." The Physical Therapist did not write a note that the physician was contacted nor was an order written to discontinue the order until the patient was a candidate for therapy. The therapist continued to re-evaluate the patient on the following dates:</p> <p>6/14/19 6/17/19 6/24/19 7/15/19 7/22/19 8/5/19 9/3/19</p> <p>On 9/4/19, the therapist performed the initial evaluation. There was no documentation that the</p>	A1123			

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A1123	<p>Continued From page 402</p> <p>physician was aware of the 3-month delay in the physician orders and delay of physical therapy. The PT evaluation was for 3 to 5x per week for therapy sessions. Review of the chart revealed the following: Week of 9/4/19 only one visit performed. A scheduled visit on 9/5/19 was missed.</p> <p>Week of 9/9/19: Patient received a visit on 9/9/19 and 9/10/19. A visit on 9/11/19 was missed. No further visits were scheduled.</p> <p>An interview with Physician #S735 was conducted on 9/18/19 in the afternoon. Physician #735 stated that she was aware that patients had not received their initial PT evaluations but had not documented it. Physician #735 reported that it was just a verbal understanding and confirmed it needs to be documented.</p> <p>An interview was conducted with Staff #S734 on 9/18/19 concerning the missed visits from 6/14/19 to 9/3/19, for Patient #432. Staff #S734 stated that she attended the interdisciplinary meetings in the NICU but confirmed she never documented that the physician was aware. Staff #S734 stated, when the babies were being seen by another discipline or had family she would not have time to go back to make up those visits. Staff #S734 confirmed, there was not enough staff to see all the patients each day.</p> <p>Patient # 433</p> <p>Review of Patient #433's chart revealed she was born on 8/11/19. An order was placed for a PT evaluation on 8/12/19. A note from PT stated the patient had an umbilical line in place and was not</p>	A1123			

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A1123	<p>Continued From page 403</p> <p>a candidate for PT. There was no note that the physician was notified or an order to discontinue. An order was found to discontinue PT on 8/16/19. Another physician order was found on 8/20/19 to perform a PT evaluation. The PT evaluation stated the patient was to be seen 1-3 x per week. The patient had missed visits on the following dates:</p> <p>8/22/19 8/29/19 8/29/19 9/4/19.</p> <p>Patient #435</p> <p>Review of Patient #435's chart revealed the patient had a physician's order for Occupational Therapy (OT) evaluation. The patient's initial evaluation was performed on 8/29/19 with a frequency of 3-5 x per week for 2 weeks. The visits were as followed:</p> <p>Initial was performed on 8/29/19.</p> <p>Week 9/2/19 had missed visits on 9/3/19 and 9/5/19. The patient had a change in condition on 9/6/19 and was moved to ICU. The patient had no visits from OT and no order was found to discontinue treatment. There was no re-evaluation done on the patient for a change in condition. Patient #435 was seen and treated by the OT on 9/12/19 and 9/13/19 but still short a visit for the week of 9/9/18.</p> <p>Review of the assignment board for 9/17/19 revealed there was 96 patients on the board for</p>	A1123			

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A1123	<p>Continued From page 404</p> <p>the day and only 5 PT's to do regular visits, initial evaluations, re-assessments, and discharges.</p> <p>An interview with Staff #S733 was conducted on 9/17/19 concerning the staffing issues in the therapy department of Hospital #2. Staff #S733 reported that they have had two issues one being inappropriate PT evaluations and staff shortage. Staff #S733 stated that he had hired a PT this week, but she was in orientation. Staff #S733 reported that he has openings he was trying to fill. Staff #S733 stated that he had recently gone to the UR committee meeting to meet with physicians concerning the inappropriate evaluation orders. Staff #S733 stated, he had not taken the issues to Quality Assessment Performance Improvement (QAPI) yet because they were working on the problem on the departmental level. Staff #S733 confirmed that they had been working on the problems for two years. Staff #733 stated that he reported data to QAPI but did not have an active Performance Improvement (PI) process.</p> <p>Review of the policy and procedures for therapy services for Hospital #2 revealed they had not been updated. Staff #S733 reported that he had been in the director position for three years but had not updated all of the policy and procedures.</p>	A1123			