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JOHNS HOPKINS ALL CHILDREN'S HOSPITAL	501 SIXTH AVENUE SOUTH SAINT PETERSBURG, FL 33701

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A 000	INITIAL COMMENTS An unannounced full federal and complaint investigation (CCR# 2018017922/FL00098488) survey was conducted at Johns Hopkins All Children's Hospital located in St. Petersburg, Fl. on 1/07/2019 through 1/11/2019, for review of all hospital Conditions of Participation. The hospital was not in compliance with the Conditions of Participation for 42 CFR 482.12 Governing Body, 42 CFR 482.21 QAPI (Quality Assurance Performance Improvement), 42 CFR 482.22 Medical Staff and 42 CFR 482.42 Infection Control. Ongoing Immediate Jeopardy was identified beginning on 9/20/2018 related to the Governing Body Condition of Participation (refer to A43).	A 000		
A 043	GOVERNING BODY CFR(s): 482.12 There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ... This CONDITION is not met as evidenced by: Based on document review and staff interview it was determined the facility's Governing Body failed to provide oversight and accountability for the Quality Assessment and Performance Improvement program (refer to A263, A273, A283, A309, and A338), failed to provide direction and oversight to ensure contracted services were appropriately monitored (refer to A84), failed to	A 043		

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

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A 043	Continued From page 1 ensure Emergency Services were provided in compliance with the Medical Staff Bylaws, failed to provide oversight and accountability for the Medical Staff (refer to A49), and failed to provide oversight and monitoring for the Infection Control Program (refer to A747, A749, and A756). Despite the facility's knowledge of complaints that alleged patient deaths due to a lack of oversight and accountability, the facility continued to implement ineffective strategies to ensure safe care. These failures resulted in a finding of ongoing Immediate Jeopardy beginning on 9/20/2018, creating a situation that is likely to result in serious injury, harm, impairment, or death to patients and requires immediate corrective action on the part of the facility.	A 043		
A 049	MEDICAL STAFF - ACCOUNTABILITY CFR(s): 482.12(a)(5) [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on document review, and staff interviews, it was determined the Governing Body failed to develop and implement an effective organizational structure to permit the timely, objective, and on-going assessment of the competence and quality of care of the medical staff. Findings include: The Medical Staff Bylaws, effective date 9/20/18, indicated each medical staff Department and Division shall be responsible for developing criteria to assure the Medical Staff and the Board	A 049		

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A 049	Continued From page 2	A 049		

that patients will receive quality and safe care. The professional criteria shall at least pertain to evidence of relevant training or experience, current competence, and ability to perform the privileges requested. The Medical Executive Committee (MEC) is empowered to act on behalf of the Medical Staff. The MEC responsibilities included: Provide a liaison between the medical Staff and the CEO, make recommendations to the Board regarding all matters relating to [medical staff] appointments, reappointments, and clinical privileges. The bylaws indicated the MEC is responsible for the Medical Staff performance-improvement activities and establishing a mechanism designed to conduct, evaluate and revise such activities.

The review of Johns Hopkins All Children's Hospital Functional Organizational Structure dated 1/3/19 revealed 10 medical staff departments lead by physicians (Interim VP of Medical Affairs, Assistant Dean Population Health, Department of Anesthesia, Department of Surgery, Department of Pediatrics, Cancer Institute, Heart Institute, IF BR Institute, MFN Institute, and the IBPS Institute) reported directly to the Vice Dean/Physician in Chief, who in turn reported to the President. There was no evidence of the Medical Executive Committee's relationship to the Medical Staff, the President or the Board of Trustees. Neither the Medical Executive Committee or the Board of Trustees were represented on the organizational chart.

The review of Johns Hopkins All Children's Hospital Medical Staff Leadership 2019 organizational chart dated 1/3/19 revealed the physician division heads for the 20 medical sub-specialties reported to the Chairman and

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A 049	Continued From page 3	A 049		

Vice Chairman of the Department of Pediatric Medicine. The physician division heads for the 12 surgical sub-specialties reported to the Interim Chair for the Department of Surgery. The Department of Pediatric Medicine and the Department of Surgery reported to the Chief of Staff, the Vice Chief of Staff and the Secretary/Treasurer, who in turn reported to the Executive Committee. The Executive Committee and the President reported to the Board of Trustees.

The review of the re-credentialing and annual appraisal criteria for the medical specialties of cardiovascular surgery, general medical cardiology, pediatrics, and pediatric critical care failed to reveal the inclusion of any objective measures that would permit a determination that the physician demonstrated current competency and quality care.

The review of the Medical Executive Committee meeting minutes for the previous 12 months failed to reveal evidence of the review of the clinical criteria for reappraisal or re-credentialing of the Medical Staff.

The review of the Board of Trustees meeting minutes for the previous 12 months failed to reveal evidence of the review of the clinical criteria for reappraisal or re-credentialing of the Medical Staff, but did reflect that the Board of Trustees approved all Medical Executive Committee recommendations for re-appointments to the Medical Staff for the requested privileges approved by the MEC.

An interview was conducted with the Senior Director of Patient Safety and Quality

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A 049	Continued From page 4 Improvement on 1/11/19 at 10:00 a.m. The Senior Director indicated the facility did not collect, track or trend any data based on objective indicators for individual physician quality of care and/or current competence. Specifically, the facility had no data related to readmissions within 30 days, unplanned returns to surgery, or morbidity and mortality by physician. An interview was conducted with the President on 1/11/19 at 10:00 a.m. The President indicated each of the department heads were responsible for developing and implementing their own quality criteria, analyzing their own data, and reporting to the Patient Safety and Quality Committee. The President confirmed the finding that neither the Medical Executive Committee, the President, nor the Board of Trustees provided oversight on this process. The President acknowledged the finding that this reporting structure and lack of Governing Body oversight was a significant factor in the previous lapses in patient care.	A 049		
A 084	CONTRACTED SERVICES CFR(s): 482.12(e)(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on document review and staff interview it was determined the Governing Body failed to ensure that contracted services are provided in a safe and effective manner. Findings include: The review of the list of Clinical Contracted	A 084		

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A 084	Continued From page 5	A 084		

Services revealed the names of 28 entities providing contracted services to the facility in 2018.

The review of the Board of Trustees meeting minutes dated 7/19/18 included a document titled Clinical Contracted Services CY (calendar year) 2017 performance evaluation summary. The document listed the 28 contracted service providers and documented the performance standards for each contracted service. The document indicated all of the performance standards for each of the 28 contracted service providers had been met.

The document indicated the Department of Pathology and Lab Medicine, and the Quality and Patient Safety Committee were responsible for managing the contract for the service provider for blood products. The document indicated establishing processes for documentation guidelines, standard operation procedures between the service provider and the facility, improving incident reporting, meetings with the service provider manager to discuss any incident reports, and updating the contract with better defined/measurable metrics were listed as improvements in progress. The review of the Board of Trustees meeting minutes for July 2018 through November 2018 failed to reveal any evidence of the reporting or monitoring of the listed improvements in progress for the blood products.

The review of the Cause Analysis Action Plan (no date indicated) described a patient experienced a seizure associated with the administration of blood products. The action plan included developing a process to have all blood product

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A 084	Continued From page 6 documents scanned into the electronic medical record system. The implementation date was 7/2/18 for inpatients and 8/2/18 for outpatients. The action plan did not include any reference to monitoring or re-evaluating the effectiveness of the plan. An interview was conducted with the Regulatory Compliance Manager on 1/10/19, who indicated she was responsible for the evaluation of the quality of contracted services. The Manager indicated the process for evaluating the quality of contracted services was that once a year she would send a form to the head of each department utilizing a contracted service and ask that person to report if he or she experienced any issues with the contracted service during the course of the previous year. The Manager indicated she was unable to produce the form for calendar year 2018 as it was currently in circulation.	A 084		
A 117	PATIENT RIGHTS: NOTICE OF RIGHTS CFR(s): 482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This STANDARD is not met as evidenced by: Based on electronic patient medical record reviews, staff interview and review of the facility's policy and procedure, the facility failed to ensure the provision of the Patient's Bill of Rights was provided to the patient or patient's representative prior to providing or discontinuing patient care for 6 of 6 patient medical records reviewed (Patient	A 117		

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#1, #2, #3, #4, #5, #6) of forty-two patients sampled.

Findings include:

On 1/9/2019 a total of 6 random medical records were reviewed, to include one closed record (#2) and five (#1, #3, #4, #5 and #6) open records. The facility was not able to demonstrate the patient or patient's representative received information related to patient rights prior to providing or discontinuing patient care for all 6 of the medical records reviewed. The review of the patient's records was completed with a facility representative to help navigate the electronic medical record. The record navigator was not able to locate this information during an interview on 1/9/2019 beginning at approximately 2:30 p.m., and first stated that nursing reviews this information with the patient. A review of the admitting documentation, completed by nursing, did not include information pertaining to patient rights. The Navigator, a Clinical Nurse Manager, then found out that admissions/registration provides this information which is contained in an admission folder with facility specific information. There was no documentation to support that this information was provided to the patient or patient's representative.

A review of the facility's policy and procedure, "Patient's Rights and Responsibilities, Management of," effective 3/6/2018 indicated "..... patients and families are provided Patient's Rights and Responsibilities information as required by law. In order to provide our patient/families with the most appropriate information, three versions of Patient's Rights and Responsibilities are available depending on who

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A 117	Continued From page 8 is provided services. The three versions available are for: Johns Hopkins All Children's Hospital, which includes hospital based service provided at the Outpatient Care Center; Johns Hopkins All Children's Home Care and All Children's Specialty Physician Clinics." The policy statement indicated, "All patients and families will be informed of their rights and responsibilities while receiving care and treatment though the services of Johns Hopkins All Children's. Patients and families will expect to carry out their responsibilities when accessing care and services at Johns Hopkins All Children's." The procedure indicates "A. The patient/legal guardian will be made aware of the Patient's Rights and Responsibilities upon admission and/or upon registration to Johns Hopkins All Children's. B. The Patient's Bill of Rights and Responsibilities are available to all patients/families as follows: 1. Hospital: Posted in the main Hospital and all Outpatient Care Centers. 2. Home Care: Provided upon admission. 3. Specialty Physician Clinical: Posted in clinic. C. Electronic versions of the Patient's Rights and Responsibilities are also available to patients and families on the Johns Hopkins All Children's website at https://www.hopkinsallchildrens.org/home." The facility failed to identify the process and document that patient's rights information was provided to the patient or patient representative. A review of the facility's "Consent for Routine Diagnostic Procedures and Medical Treatment" was also conducted and failed to include information related to the provision of Patient Rights.	A 117		
A 263	QAPI	A 263		

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A 263	Continued From page 9 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. This CONDITION is not met as evidenced by: Based on a review of the facility's documents, policies and procedures, and staff interviews it was determined the facility failed to develop, implement and maintain an effective, on-going, data-driven quality assessment and performance improvement (QAPI) program that was integrated into all departments of the facility. The facility failed to ensure objective quality indicator data was collected, tracked, trended, and analyzed across the organization to facilitate the process of providing quality patient care and improving patient safety (refer to A273). The facility failed to ensure collected data was utilized to identify opportunities for improvement that were prioritized on the basis of high-risk, high-volume, or problem prone areas that affected health outcomes, patient safety, and quality of care (refer to A283). The Governing Body failed to	A 263		

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A 263	Continued From page 10 ensure the management of the organization was structured to ensure the effective implementation of a data-driven quality improvement organization that measurably improved the facility's demonstrated ability to provide quality patient care and improve patient safety (refer to A309).	A 263		
A 273	DATA COLLECTION & ANALYSIS CFR(s): 482.21(a), (b)(1),(b)(2)(i), (b)(3) (a) Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes ... (2) The hospital must measure, analyze, and track quality indicators ... and other aspects of performance that assess processes of care, hospital service and operations. (b)Program Data (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization. (2) The hospital must use the data collected to-- (i) Monitor the effectiveness and safety of services and quality of care; and .... (3) The frequency and detail of data collection must be specified by the hospital's governing body. This STANDARD is not met as evidenced by: Based on document review and staff interview it	A 273		

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was determined the facility failed to ensure objective quality indicator data related to medical care was collected, tracked, trended, and analyzed across the organization to facilitate the process of providing quality patient care and improving patient safety.

Findings include:

The Quality and Patient Safety Plan (the Plan) FY (fiscal year) 2019, approved September 20, 2018 was signed by the Patient Safety Officer and the Chair, Board Quality and Patient Safety Committee. The Plan indicated the Patient Safety and Quality Council reported to the Board of Trustees through the Board Quality and Patient Safety Committee. The plan indicated several Medical Staff committees received or provided reports regarding patient safety and quality. The plan included documentation that the Clinical Practice Council oversees the prioritization, development, and deployment of clinical guidelines. Each department, program, and institute conducts quality improvement and safety initiatives that are aligned with the strategic priorities of the organization and/or the population served by that department, program, or institute.

Review of the facility's current written agreement with the OPO (organ procurement organization), signed with the most recent addendum on 1/23/2018, revealed section G. Activity Data Review, Reporting and Quality Assessment (QA) and Improvement (QI) stated "G.1 At least annually, the Foundation shall provide Donor Hospital specific data with the appropriate Donor Hospital personnel for the purposes of quality assessment (QA) and improvement (QI), process evaluation, and to analyze outcomes of potential

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referral/donor situations, allowing for a collaborative plan of corrective action when indicated."

Review of the facility's Board Quality and Patient Safety Committee meeting minutes revealed the last meeting in which specific data was provided was 1/19/2017. Review of requested documentation revealed the OPO provided data for calendar years 2017 and 2018. There was no evidence the data was provided to the facility's Board Quality and Patient Safety Committee for integration into the hospital's QAPI (Quality Assurance Performance Improvement) program.

An interview was conducted with the Interim Vice President of Medical Affairs on 1/8/19 regarding the oversight of medical quality of care. The Vice President indicated the Medical Quality of Care Committee would review individual cases that were brought to their attention, but they had no historical data related to that particular problem or that particular physician. He indicated no data was collected or reported as a result of the Committee's review of any individual case.

An interview was conducted with the Interim Chief Executive Officer (CEO), the Senior Vice President Patient Safety Officer, the Interim Vice President of Medical Affairs, the Senior Director of Patient Safety and Quality/Interim Patient Safety Officer, the General Counsel, the Chief Operating Officer, the Regulatory Compliance Manager, the Vice President for Quality and Risk Management Johns Hopkins and other interested parties on 1/11/19 at 9:30 a.m. The Senior Director of Patient Safety and Quality confirmed that each clinical division and department develops their own criteria and quality indicators,

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A 273	Continued From page 13 and performs their own investigations of any events. The Senior Director indicated there is no organization wide, integrated assessment based on the tracking, trending, and analysis of objective data used to identify high frequency or high acuity concerns related to the overall quality of care and patient safety provided by the hospital. She indicated the facility has no historical data on objective indicators of quality of care that have been tracked, trended, and analyzed such as unplanned returns to surgery, patient deaths, or morbidity and mortality statistics by physician. The CEO confirmed the findings.	A 273		
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 ensure that improvements are sustained.	A 283		

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This STANDARD is not met as evidenced by:
Based on document review and staff interview it was determined the facility failed to ensure that collected data was utilized to identify opportunities for improvement that were prioritized on the basis of high-risk, high-volume, or problem prone areas that affected health outcomes, patient safety, and quality of care.

Findings include:

The Quality and Patient Safety Plan (the Plan) FY (fiscal year) 2019, approved September 20, 2018 was signed by the Patient Safety Officer and the Chair, Board Quality and Patient Safety Committee. The Plan indicated the Patient Safety and Quality Council reported to the Board of Trustees through the Board Quality and Patient Safety Committee. The Plan indicated several Medical Staff committees received or provided reports regarding patient safety and and quality. The plan included documentation that the Clinical Practice Council oversees the prioritization, development, and deployment of clinical guidelines. Each department, program, and institute conducts quality improvement and safety initiatives that are aligned with the strategic priorities of the organization and/or the population served by that department, program, or institute.

The plan did not include any evidence that the selection of indicators, quality improvement projects, or the development of criteria were based on any review of the tracking and trending of objective data that identified measurable concerns or issues that were high frequency or

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high acuity, and was limited primarily to reporting requirements defined by the regulatory or the accrediting agencies.

The review of the Quality and Patient Safety Dashboard dated 12/18/18 displayed data for Serious Harm Events, defined as Central Line - Associated Blood Stream Infections (CLABSI), Catheter-Associated Urinary Tract Infections (CAUTI), Surgical Site Infections(SSI) of Spinal Fusions, Ventricular Shunts, and Cardiac Surgery, Hand Hygiene, Pressure Injury, Falls with moderate or greater injury, Peripheral IV (PIV) infiltrates, Adverse Drug Events (ADE), Unplanned Extubations in ICU, Venous Thromboembolism, Readmissions within 7 days, Employee Harm, Influenza Immunizations, seven indicators for Emergency Center throughput, and Patient Satisfaction. For each reported month the report indicated whether the data indicated the facility was performing at, above, or below the target for each indicator. The report displayed the statistic for the previous year's (2017) performance for each indicator. The 2018 goals for each indicator were established to reflect improvement over the 2017 performance. The report also displayed Year To Date statistics, which aggregated the data to provide an overall indication of the performance level of each indicator on a year to date basis.

November 2018 was the most recent month for which data was reported, along with Year To Date statistics. The report displayed the year-to-date statistics for the indicators CLABSI, CAUTI, SSIs for Spinal Fusions and Ventricular Shunts, Hand Hygiene, Pressure Injuries, Peripheral IV Infiltrates, Unplanned Extubations in ICUs, Serious Employee/Staff Harm, and Influenza

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A 283	Continued From page 16 Immunizations. The Year-To- Date data showed performance for those indicators was worse in 2018 than in 2017. The review of the Patient Safety and Quality Council Meeting Minutes dated 12/12/18 included documentation a comprehensive dashboard review was presented to the Council. The area designated to indicate Action Plan Responsibilities and Time Frames next to the minutes of the presentation was blank. The Regulatory Compliance Manager confirmed the findings in an interview conducted on 1/11/19 at approximately 2:00 p.m.	A 283		
A 309	QAPI EXECUTIVE RESPONSIBILITIES CFR(s): 482.21(e)(1), (e)(2), (e)(5) The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: 1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained . (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated. (5) That the determination of the number of distinct improvement projects is conducted annually.	A 309		

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This STANDARD is not met as evidenced by:
Based on document review and staff interview it was determined that the Governing Body failed to ensure the management of the organization was structured to ensure the effective implementation of a data-driven quality improvement organization that measurably improved the facility's demonstrated ability to provide quality patient care and improve patient safety.

Findings include:

The Quality and Patient Safety Plan dated 9/20/18 indicated that the governing body was responsible for assuring that the Quality and Patient Safety Plan was effective and in compliance with regulatory requirements.

The organizational chart included in the plan displayed the committees for Environment of Care, Continuous Regulatory Readiness, Quality Council, Safety Coaches, Infection Prevention/Antimicrobial Stewardship, and High Value Care reported to the Patient Safety and Quality Council. The Patient Safety and Quality Council received input from the Ambulatory Networks Council, the Advocacy Council, the Clinical Practice Council, the Research Council, the Education Counsel, the Cultures and Engagement Council, the Medical Staff Committees, the Johns Hopkins Medical Pediatric Quality Group, and the Johns Hopkins Quality, Safety, and Service Executive Committee. The Patient Safety and Quality Council reported to the Board Quality and Patient Safety Committee, who in turn reported to the Board of Trustees. The Risk Management department was not indicated

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on the organizational chart included included in the Quality and Safety Plan. Nothing in the plan addressed the manner in which objective data would be tracked, trended, and analyzed across the organization as a whole in order to identify areas of concern, or monitor the effectiveness of quality improvement projects or plans of correction.

The Johns Hopkins All Children's Hospital Functional Organizational Structure dated 1/3/18 displayed the Risk Management and Insurance Department as the last item in the lower right hand corner of the chart, reporting to Legal Affairs, that in turn reported to the Vice Dean/Physician in Chief. There was no evidence of any lines of communication or accountability between the Risk Management Department and any of the 17 committees, councils, and departments shown on the organizational chart as being responsible for the prioritization, development and deployment of clinical guidelines.

The plan defined the purpose, objectives, membership, meeting frequency, and reporting structures of the Board Quality and Patient Safety Council, Patient Safety Council, the Quality Sub-Council, and Safety Coaches. The plan defined the roles and responsibilities of the Medical Staff, Senior Leadership, Patient Safety Officer, Senior Director, Institute, Department and Service-line Directors, and Employees. The responsibilities of the Medical Staff were presented as Department Chairpersons shall be accountable for their assigned divisions and sections appropriate, quality, and safe patient care services.

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The plan did not include any evidence that the selection of indicators, quality improvement projects, or the development of criteria were based on any review of the tracking and trending of objective data that identified measurable concerns or issues that were high frequency or high acuity.

An interview was conducted with the Interim Chief Executive Officer (CEO), the Senior Vice President Patient Safety Officer, the Interim Vice President of Medical Affairs, the Senior Director of Patient Safety and Quality/Interim Patient Safety Officer, the General Counsel, the Chief Operating Officer, the Regulatory Compliance Manager, the Vice President for Quality and Risk Management Johns Hopkins and other interested parties on 1/11/19 at 9:30 a.m. The Senior Director of Patient Safety and Quality confirmed that each clinical division and department develops their own criteria and quality indicators, and performs their own investigations of any events. Each clinical division and department develops their own action plans, implements, and evaluates the plans for effectiveness, and reports whatever information they determine is relevant or necessary through the channels shown on the organizational chart in the Quality and Patient Safety Plan. The Senior Director indicated there is no organization wide, integrated assessment based on the tracking, trending, and analysis of objective data used to identify high frequency or high acuity concerns related to the overall quality of care and patient safety provided by the hospital. The Senior Director indicated she did not have access to any Risk Management reports or data collection in the 15 months she has been in her position at the facility. She indicated the facility has no historical data on objective

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A 309	Continued From page 20 indicators of quality of care that has been tracked, trended, and analyzed such as unplanned returns to surgery, patient deaths, or morbidity and mortality statistics by physician. The CEO confirmed the findings.	A 309		
A 338	MEDICAL STAFF CFR(s): 482.22 The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. This CONDITION is not met as evidenced by: Based on document review and staff interview it was determined the facility failed to ensure the medical staff was in compliance with the Medical Staff bylaws with regard to ensuring the reappraisal process and the re-credentialing process effectively determined the current competency and abilities of the medical staff members. The Medical Staff failed to be fully accountable to the governing body for the quality of care it provided to patients (refer to A347). The facility failed to ensure the re-credentialing process met the Medical Staff Bylaws requirement to develop criteria to ensure safe care through evidence of current competence and ability to perform requested privileges (refer to A355).	A 338		
A 347	MEDICAL STAFF ORGANIZATION & ACCOUNTABILITY CFR(s): 482.22(b)(1), (2), (3) The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.	A 347		

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(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:
(i) An individual doctor of medicine or osteopathy.
(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.
(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

This STANDARD is not met as evidenced by:
Based on a review of documents and staff interview, the facility failed to ensure the Medical Staff was fully accountable to the governing body for the quality of care it provided to patients.

Findings included:

The Medical Staff Bylaws, effective date 9/20/18, indicated each medical staff Department and Division shall be responsible for developing criteria to assure the Medical Staff and the Board that patients will receive quality and safe care. The professional criteria shall at least pertain to evidence of relevant training or experience, current competence, and ability to perform the privileges requested. The Medical Executive Committee (MEC) is empowered to act on behalf

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of the Medical Staff. The MEC responsibilities included: Provide a liaison between the medical Staff and the CEO, make recommendations to the Board regarding all matters relating to [medical staff] appointments, reappointments, and clinical privileges. The bylaws indicated the MEC is responsible for the Medical Staff performance-improvement activities and establishing a mechanism designed to conduct, evaluate, and revise such activities.

The review of Johns Hopkins All Children's Hospital Functional Organizational Structure dated 1/3/19 revealed 10 medical staff departments lead by physicians (Interim VP of Medical Affairs, Assistant Dean Population Health, Department of Anesthesia, Department of Surgery, Department of Pediatrics, Cancer Institute, Heart Institute, IF BR Institute, MFN Institute, and the IBPS Institute) reported directly to the Vice Dean/Physician in Chief, who in turn reported to the President. There was no evidence of the Medical Executive Committee's relationship to the Medical Staff, the President or the Board of Trustees. Neither the Medical Executive Committee or the Board of Trustees were represented on the organizational chart.

The review of Johns Hopkins All Children's Hospital Medical Staff Leadership 2019 organizational chart dated 1/3/19 revealed the physician division heads for the 20 medical sub-specialties reported to the Chairman and Vice Chairman of the Department of Pediatric Medicine. The physician division heads for the 12 surgical sub-specialties reported to the Interim Chair for the Department of Surgery. The Department of Pediatric Medicine and the Department of Surgery reported to the Chief of

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Staff, the Vice Chief of Staff and the Secretary/Treasurer, who in turn reported to the Executive Committee. The Executive Committee and the President reported to the Board of Trustees.

The Johns Hopkins All Children's Hospital Functional Organizational Structure dated 1/3/18 failed to provide evidence of any lines of communication or accountability between any of the 17 committees, councils, and departments shown on the organizational chart as being responsible for the prioritization, development, and deployment of clinical guidelines.

The Senior Director of Patient Safety and Quality confirmed that each clinical division and department develops their own criteria and quality indicators, and performs their own investigations of any events. Each clinical division and department develops their own action plans, implements and evaluates the plans for effectiveness, and reports whatever information they determine is relevant or necessary through the channels shown on the organizational chart in the Quality and Patient Safety Plan. The Senior Director indicated there is no organization wide, integrated assessment based on the tracking, trending, and analysis of objective data used to monitor the overall quality of care and patient safety provided by the hospital. She indicated the facility has no historical data on objective indicators of quality of care that has been tracked, trended, and analyzed such as unplanned returns to surgery, patient deaths, or morbidity and mortality statistics by physician. The CEO confirmed the finding the Medical Staff has not been effectively accountable to the governing body.

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A 355	MEDICAL STAFF PRIVILEGING CFR(s): 482.22(c)(2) [The bylaws must:] (2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.) This STANDARD is not met as evidenced by: Based on document review and staff interview it was determined the facility failed to ensure the re-credentialing process met the Medical Staff Bylaws requirement to develop criteria to ensure safe care through evidence of current competence and ability to perform requested privileges for 1 sampled member of the medical staff (Physician A), of a total of 2 active members with current privileges in cardiovascular surgery. Findings include: The Medical Staff Bylaws, effective date 9/20/18, indicated each Department and Division shall develop criteria for the granting of Clinical Privileges designed to assure the Medical Staff and the Board that patients will receive quality and safe care. The criteria shall at least pertain to evidence of relevant training or experience, current competence, and ability to perform the privileges requested (page 18, section 6.5). The review of the document titled Cardiovascular Surgery Delineation of Privileges published 5/4/17 included the evidence necessary to satisfy the requirements of Clinical Experience for reappointment to the medical staff with privileges in cardiovascular surgery was evidence of 100 open cases per 2 year cycle.	A 355		

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The credentialing file for Physician A included a list of 244 surgical cases with the date and description of the procedure provided by a community hospital in another city. The document did not indicate whether Physician A was the primary surgeon or the assistant surgeon for the listed cases.

The facility was unable to comply with a request to produce evidence of any objective measurement of the current competency and ability to perform the requested privileges, such as outcomes analysis or morbidity and mortality statistics, for the 244 surgical procedures performed at an outside facility and submitted to satisfy the re-credentialing criteria for privileges in cardiovascular surgery.

The recredentialing file for Physician A revealed the list of requested privileges was signed electronically by the physician on 12/12/17. The list included a request to perform general thoracic surgery, vascular surgery, adult cardiac including use of cardiopulmonary bypass, pediatric cardiac including use of cardiopulmonary bypass, and neonatal cardiac including use of cardiopulmonary bypass, pediatric heart transplants, and bronchoscopy. The Acknowledgement of Applicant statement above the physician's electronic signature read, "I have requested only those privileges for which by education, training, current experience, and demonstrated competency I want to perform and that I wish to exercise at All Children's Hospital. Check boxes next to each requested privilege and the electronic signature of the Division Chair dated 1/24/18 indicated the Division Chair approved all requested privileges.

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A 355	Continued From page 26 Additional documentation revealed Physician A was granted all requested privileges and re-appointed as an active member of the medical staff for the two year period from 3/1/18 through 2/29/20. An interview was conducted with the Interim Vice President of Medical Affairs on 1/8/19 at the time of the review of the credentialing files. The Vice President confirmed the finding the established criteria for granting clinical privileges in cardiovascular surgery to members of the medical staff applying for reappointment failed to meet the standard to ensure current competence and ability to perform the requested procedures as required by the Medical Staff Bylaws. An interview was conducted with the Interim Chief Executive Officer (CEO), the Senior Vice President Patient Safety Officer, the Interim Vice President of Medical Affairs, the Senior Director of Patient Safety and Quality/Interim Patient Safety Officer, the General Counsel, the Chief Operating Officer, the Regulatory Compliance Manager, the Vice President for Quality and Risk Management Johns Hopkins and other interested parties on 1/11/19 at 9:30 a.m. The Senior Director indicated indicated the facility has no historical data on objective indicators of quality of medical care that has been tracked, trended, and analyzed such as unplanned returns to surgery, patient deaths, or morbidity and mortality statistics by physician. The CEO confirmed the findings.	A 355		
A 466	CONTENT OF RECORD: INFORMED CONSENT CFR(s): 482.24(c)(4)(v)	A 466		

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[All records must document the following, as appropriate:]
Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

This STANDARD is not met as evidenced by:
Based on review of the medical record, review of facility policy, and staff interview it was determined the facility failed to ensure a properly executed informed consent form was obtained for a procedure for one (#35) of forty sampled patients.

Findings include:

Review of the facility policy, "Informed Consent for Medical/Surgical Procedures," with an effective date of 4/2/2018, stated it is the practitioner's responsibility to obtain informed consent from the patient/parent(s)/legal guardian(s) prior to providing care or treatment to patients, except in medical emergencies, and to provide adequate information so that the patient/parent(s)/legal guardian(s) may make educated and informed decisions about proposed care. The policy stated telephone consent may be obtained from a person who has legal authority to consent but who is unable to present in person. The policy stated abbreviations may not be used to describe the intervention on the consent form.

Review of the medical record for patient #35 revealed the patient, a minor child, was admitted on 12/13/2018. Review of the record revealed informed consent, dated 12/15/2018 at 3:11 pm, for Lumbar Puncture to "r/o HSV & Meningitis in

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A 466	Continued From page 28 CSF fluid." There was no explanation of the abbreviations documented on the informed consent. Review of the informed consent, dated 12/15/2018 at 3:11 pm, revealed the documentation written for relation to patient was "phone consent." There was no documentation from whom the consent was obtained. Interview with the Director of Accreditation & Survey Readiness on 1/10/2019 at approximately 2:30 pm confirmed the above findings.	A 466		
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 safety and quality. This STANDARD is not met as evidenced by: Based on observation and interview it was determined the facility failed to secure 9 of 10 portable oxygen e-cylinders within 2 wheeled carts to ensure a safe environment. Findings include: On 1/7/2019, day one of survey, a tour of the following patient care areas revealed six [6] of six [6] portable Oxygen E-Cylinders not secured within 2 wheeled carts as follows: - 3 of 3 unsecured in the Emergency Department - 1 of 1 unsecured in NICU [Neonatal Intensive Care Unit] South 6th floor - 1 of 1 unsecured in NICU [Neonatal Intensive Care Unit] North 6th floor - 1 of 1 unsecured in PICU [Pediatric Intensive Care Unit] 5th floor On 01/09/2019, day three of survey, additional	A 724		

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A 724	Continued From page 29 oxygen e-cylinders were found to be unsecured within 2 wheeled carts as follows: - 1 of 1 unsecured in procedure room 2351 - 1 of 2 unsecured in clean utility room 1154, also room not identified as a storage room for oxidizing gas. - 1 of 1 unsecured in patient room 115 An interview was conducted during the tour with the Director of Pediatric Emergency Services, Trauma, Lifeline, Nursing Supervision, Workforce Management and Respiratory Therapy and confirmed the findings.	A 724		
A 747	INFECTION CONTROL 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 CONDITION is not met as evidenced by: Based on policy and procedure review, document review, direct observation, and staff interviews, it was determined the facility failed to ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training incorporated infection control problems identified on a routine basis. The facility failed to follow current Infection Control standards for cleaning patient care areas and equipment (refer to A749). The facility failed to identify, investigate, and control potential environmental sources of patient hospital acquired infections (HAI's) (refer to A749). The facility failed to report specific findings of ongoing environment of care	A 747		

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A 747	Continued From page 30 monitoring to QAPI, Medical staff, and Chief Executive Officer (refer to A756).	A 747		
A 749	INFECTION CONTROL PROGRAM CFR(s): 482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on policy review, document review, direct observation, and staff interviews, it was determined the facility failed to provide a sanitary environment and identify, investigate and prevent potential transmission of infections associated with environmental sources. Findings include: Hand Hygiene: Review of the facility Infection Prevention Program annual report for calendar year 2017 and Plan for calendar year 2018, revealed concerns were raised at the end of 2016 regarding hand hygiene tracking and therefore the facility implemented a new tracking system in 2017. The goal for 2018 was to sustain hand hygiene compliance at a rate of 96%. The following inpatient hand hygiene compliance percentages were obtained in 2017: January 2017- 93.1% February 2017-99.4% March 2017-99.0% April 2017-98.1%	A 749		

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May 2017-98.5%
June 2017-98.9%
July 2017-99.2%
August 2017-94.4%
September 2017-97.5%
October 2017-95.8%
November 2017-99.4%
December 2017-94.0%
2017 Year average = 97.3%

According to the data collected for 2018 hand hygiene compliance rates decreased from 2017 and fell below the facility's goal range.
January 2018- 96.1%
February 2018-93.8
March 2018-94.5%
April 2018-94.3%
May 2018-97.6%
June 2018-87.9%
July 2018-84.2%
August 2018-85.5%
September 2018-87.9%
October 2018-91.4%
November 2018-84.3%
December 2018-93.7%
2018 Year to date average=90.9%
Based on documentation provided, hand hygiene compliance decreased 6.4% in 2018.

In an interview with Infection Prevention ARNP Staff H at 11:45 a.m. on 1/11/2019, she stated that hand hygeine auditing was being conducted but the auditing began prior to the low hand hygeine scores and no modifications have been put in place.

Review of the Quality and Patient Safety Plan for 2019 that was presented to the Quality Board on 09/20/18, revealed it included metrics on

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decreasing HAIs (hospital acquired infections) for 2019 but did not include the results on the decreasing hand hygiene compliance or specifically how the facility planned to increase hand hygiene compliance. The 2019 Quality and Safety Plan requires an infection control update once per year.

Surgical Site Infections:
According to review of the facility report titled "Hospital Acquired Infections: Trends, Challenges and Action Plans" (no date), the facility identified specific concerns related to surgical site infections on the cardiovascular intensive care unit (CVICU). It was noted there was an increase in surgical site infections for 2017 and 2018 on this unit. The infection site identified was the mediastinum (the chest cavity).
According to the document titled Infection Prevention Program annual report for calendar year 2017 and plan for calendar year 2018, the risk assessment showed the probability of an infection from spinal surgical site as one (1) and the probability of an infection cerebral spinal fluid (CSF) shunt as one (1) for 2018.

A review of the 2017 through 2018 surgical site infection list revealed the facility reported eleven (11) infections from the following sites:
1. Four were from the mediastinum surgical site. Of the four infections, two were from one surgeon and two were from another surgeon. All four of these infections were identified in 2017.
2. Three were from the spinal surgical site. Of the three infections, two were from one surgeon and one was from another surgeon. All three of these infections were identified in 2018.
3. Four were from the cerebral spinal fluid (CSF) shunt. Of the four infections, three were from one

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surgeon and one was from another surgeon. Two of these infections were identified in 2017 and two were identified in 2018.

According to an interview with the IP (infection prevention) nurse on 1/8/19 at 1:30 p.m., education was provided to some surgeons regarding surgical site infections on 03/20/2018, titled "Surgical Wound Care Protocol in Cardiac Surgery Patients." This training was provided to the surgeons and operating room registered nurses (RN's) however, according to the sign-in sheet, the training was not attended by any of the surgeons listed on the 2017-2018 surgical site infection list.

There was no documentation on the trending of specific organisms related to surgical site infections (SSI) for the spinal surgical site or the cerebral spinal fluid (CSF) shunt site listed on the 2017-2018 SSI (surgical site infection) list. There was no evidence that all surgical site data was analyzed and presented to QAPI or the Medical Executive Committee (MEC). The IP nurse further stated the facility has not made a connection regarding the cause of the listed hospital acquired infections (HAIs).

Environment of Care (EOC):
According to an interview with the IP nurse on 1/9/19 at 11:30 a.m., the process of monitoring the facility's environment for potential or actual infection related concerns was switched from the infection control department to environmental services (EVS) beginning in 2018. The previous tracking sheets, photos, and emails to department managers, which were being completed by the IP nurse, were now being completed by EVS and safety.

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The current environment of care (EOC) tracking report provided by EVS, listed all four quarters of 2018, and is broken down by area of the facility checked and impacted, including infection control areas. The report did not deliniate the identified issues by: staff, exact location, corrective action, or follow-up needed.

An example of a listed category on the EOC checklist that was checked each quarter of 2018 is "Medications/medical supplies-have no expired dates." The 2018 compliance results for all four quarters reveal the following:
1. Quarter 1=100%
2. Quarter 2=96.55%
3. Quarter 3=100%
4. Quarter 4=66.67% (testing completed on 10/3/18)

It was not clear by the report what unit this occurred on or how it was corrected.

On 1/11/19 at 11:45 a.m. an interview was conducted with the Director of Safety regarding the test results above and actions taken. According to the director, the process included emailing the manager of the specific unit on 10/3/18 with a request for corrective action by 11/2/18. The director provided documentation that the issue was resolved on 11/16/18 (44 days after being identified). There was no documentation, within the tracking program, of the specific action/s taken or a prevention plan. The Director of Safety confirmed infection control staff are not included in the email of findings or the action plan.

The IP nurse confirmed infection control is not included in the email correspondence to unit

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managers, even when the subject of concern is infection control. The IP nurse confirmed that the infection control department is not involved in the process of evaluating the environment of care.
Review of an email dated 10/24/17 at 11:32 a.m., from the IP nurse to the manager of EVS, revealed the facility uses Adenosine triphosphate (ATP) testing to determine if the surfaces of various high contact areas throughout the patient and visitor areas of the facility are clean and acceptable for next patient use. ATP is a rapid testing method, whereby an item is swabbed to quickly assess the cleanliness of surfaces. According to the IP nurse, a reading under 250 relative light units (RLU), indicates the item is ready for patient use. The following out of range results were obtained on 10/24/17 and emailed to the Director of EVS:
1. Location: Outpatient Lobby- Three different wheelchairs were tested and yielded results of 450 RLU, 342 RLU, and 714 RLU.
2. Location: Post Anesthesia Care Unit (PACU)-Four different wheelchairs tested and yielded results of 878 RLU, 332 RLU, 509 RLU, and 263 RLU.

According to an interview with the director of EVS on 1/9/19 at 11:30 a.m., training was provided only to the two EVS employees responsible for cleaning wheelchairs during that time. There is no documentation that this training occurred.

According to the IP nurse, infection control does not report the EOC rounding data to quality, Medical staff, or the CEO. The director of safety was not able to provide documentation that the data was presented to the above groups.

According to the IC nurse, there is not a policy or

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procedure on surveillance rounding or the ATP testing and reporting process.

Facility policy titled "Scope of Service-Infection Prevention Program" #08-122 states infection prevention and control are responsible for developing policies governing control of infections and communicable diseases.

During a tour of the main lobby area on 10/10/19 at 11:30 a.m., with the IP nurse and manager of Patient Safety and Quality, it was discovered that the space where the uncleaned wheelchairs are kept is an unmarked and unsecured area close to where patients and visitors would enter the building. When questioned about individuals taking the uncleaned wheelchairs from this area, the IP nurse confirmed that patients and valet staff could take wheelchairs from this area.

While on tour on with the IP nurse and manager of Patient Safety and Quality, the following random ATP testing and out of acceptable range results were obtained by the IP nurse:
1. Wheelchair main lobby- 305 RLU
2. Seventh floor children's toy room
a. Pink toy car (seat of car tested)-8986 RLU
b. "Rockem Sockem" toy (handles)-1853 RLU
The IP nurse confirmed the above results are unacceptable and increase the risk of transmitting communicable diseases. The toy room was shut for use at the time of the tour until proper cleaning was complete.

According to facility policy titled Cleaning, Disinfection, and Storage of Non-Disposable Medical Equipment, Devices, Supplies, and Toys, #CLNPOL012 dated 06/29/2018, toys can be a source of hospital-associated infection: they may

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be colonized with infectious pathogens, therefore must be cleaned in between patient use. There is not a current tracking system to identify if the toys in the toy room are clean and ready for use.

On 1/7/19 at 11:30 a.m., a tour of the outpatient rehabilitation facility was conducted. During the tour, in the feeding room, it was noted that inside a patient refrigerator labeled "Therapy room 3112 NUT. REFRIG 69-152" was a zip lock bag labeled "opened 9/26" with food type contents in it and a 14 ounce container of strawberry ice cream with a pink colored liquid substance leaking from the bottom of the container.

According to an interview with the Director of Rehabilitation on 1/7/19 at 11:45 a.m., the policy is to discard any patient food items after one week.

The director confirmed it was a patient's food in the zip lock bag and the food and ice cream should have been thrown out.

In the occupational rehabilitation kitchen was patient refrigerator, labeled "Room 3175A ADL KITCHEN REFRIDG. 213-17", with a sign on the door stating it was for patient use only. Within this refrigerator, on the top shelf on the door, were two boxes of a product titled "ROXYLAN 50/50 MIX ELSTROM 240G" the boxes had handwriting on them with the words "Not for consumption". The first box had an expiration date of 2018/03 and the second box had an expiration of 2018/08/04. Both boxes of product were expired. The two boxes of Roxylan were sitting on the top shelf of the refrigerator door, next to 3 containers of cake frosting.

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The director confirmed these products should not be kept in the patient refrigerator and should have been discarded when they expired.

On 1/08/2019 at approximately 10:30a.m., a tour of sterile processing revealed sprinklers loaded with dust, debris and corrosion. Cross contamination observed in Room 2351 with anesthesia cart waste anesthesia gas disposal (WAGD) line connected to vacuum line. An interview during the tour with maintenance, and department leads confirmed the findings.

On 1/9/19 at 10:15 a.m., a tour was conducted on 7 North. During the tour, an interview was conducted with a member of housekeeping at 11:00 a.m. The housekeeping staff described the responsibilities of housekeeping, including cleaning of the patient rooms. According to the housekeeper, the room is wiped down with a cleaning cloth called Oxivir and must remain wet on the surface for 2 minutes.

According to facility policy "Cleaning, Disinfecting, and Storage of Non-Disposable Medical Equipment, Devises, Supplies, and Toys" # CLNPOL012, effective 06/29/18, "Contact time-The amount of time the disinfectant has to remain wet on the surface(s) of the clean object/instrument to completely disinfect that object is 5 minutes for Oxivir and Bleach and alcohol is 5 seconds".

Policies:
A review of all facility infection control related policies provided revealed four policies and nine accompanying appendixes have not been reviewed by infection control since March 2016. The facility failed to incorporate the infection

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A 749	Continued From page 39 prevention specialist in its active surveillance and to maintain a sanitary environment in all areas of the hospital.	A 749		
A 756	INFECTION CONTROL LEADERSHIP RESPONSIBILITIES CFR(s): 482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services The chief executive officer, the medical staff, and the director of nursing must-- (1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas. This STANDARD is not met as evidenced by: Based on policy and procedure review, document review, and staff interviews, it was determined the facility failed to ensure that the hospital-wide quality assessment and performance improvement (QAPI) program identified infection control problems and reported specific findings on an ongoing basis to the Chief Executive Officer (CEO) and Medical staff as evidenced by the following: Findings include: According to review of facility report titled	A 756		

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"Hospital Acquired Infections: Trends, Challenges and Action Plans" (no date), the facility identified specific concerns related to surgical site infections on the cardiovascular intensive care unit (CVICU). It was noted there was an increase in surgical site infections for 2017 and 2018 on this unit. The infection site identified was the mediastinum (the chest cavity).
According to the Infection Prevention Program annual report for calendar year 2017 and plan for calendar year 2018, the risk assessment showed the probability of an infection in 2018 from spinal surgical site as one (1) and the probability of an infection cerebral spinal fluid (CSF) shunt as one (1) for 2018.

Review of the 2017 through 2018 surgical site infection list, the facility reported eleven (11) surgical site infections:
1. Four were from the mediastinum surgical site. Of the four infections, two were from one surgeon (Physician B) and two were from another surgeon (Physician C). All four of these infections were identified in 2017.
2. Three were from the spinal surgical site. Of the three infections, two were from one surgeon (Physician E) and one was from another surgeon (Physician D). All three of these infections were identified in 2018.
3. Four were from the cerebral spinal fluid (CSF) shunt. Of the four infections, three were from one surgeon (Physician E) and one was from another surgeon (Physician G). Two of these infections were identified in 2017 and two were identified in 2018.

According to an interview with the IP (infection prevention) nurse on 1/8/19 at 1:30 p.m., education was provided to some surgeons,

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A 756	Continued From page 41	A 756		

regarding surgical site infections on 03/20/2018, titled "Surgical Wound Care Protocol in Cardiac Surgery Patients". This training was provided to the surgeons and operating room registered nurses (RNs) however, according to the sign-in sheet, the training was not attended by any of the surgeons listed on the 2017-2018 surgical site infection list. There was no evidence of additional education on surgical site infections provided to the surgeons.

There is no documentation that the above findings were reported to QAPI (quality assurance and performance improvement), the CEO, and medical staff in order to ensure the implementation of a successful corrective action plan.

According to an interview with the IP nurse on 1/9/19 at 11:30 a.m., the process of monitoring the facility environment for potential or actual infection related concerns was switched from the infection control department to environmental services (EVS) beginning in 2018. The previous tracking sheets, photos, and emails to department managers, which were being completed by the IP nurse, were now being completed by environmental services and safety staff.

The IP nurse confirmed infection control is not included in the email correspondents to unit managers, even when the subject of concern is infection control.

According to the IP nurse, infection control does not report the environment of care rounding data to QAPI, Medical staff, or the CEO. The Director of Safety was not able to provide documentation

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A 756	Continued From page 42 that the data was presented to the above groups. The 2019 Quality and Safety Plan requires the board of quality to receive an infection control committee update only once per year. The facility leadership failed to ensure the problems identified by environmental services and infection control and prevention were presented, along with ensuring the implementation of a successful corrective action plan.	A 756		
A 843	REASSESSMENT OF DISCHARGE PLANNING PROCESS CFR(s): 482.43(e) The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs. This STANDARD is not met as evidenced by: Based on review of facility documents for discharge planning process reassessment and staff interview it was determined the facility failed to ensure activities and reassessment of the facility's discharge planning process was reported to the Board Quality and Patient Safety Committee for integration into the hospital-wide QAPI (Quality Assurance Performance Improvement) program. Findings include: The Quality and Patient Safety Plan (the Plan) FY (fiscal year) 2019, approved September 20, 2018 was signed by the Patient Safety Officer and the Chair, Board Quality and Patient Safety	A 843		

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A 843	Continued From page 43	A 843		

Committee. The Plan indicated the Patient Safety and Quality Council reported to the Board of Trustees through the Board Quality and Patient Safety Committee. The plan indicated several Medical Staff committees received or provided reports regarding patient safety and quality. The plan included documentation the Clinical Practice council oversees the prioritization, development, and deployment of clinical guidelines. Each department, program, and institute conducts quality improvement and safety initiatives that are aligned with the strategic priorities of the organization and/or the population served by that department, program, or institute.

The plan did not include any evidence the selection of indicators, quality improvement projects, or the development of criteria were based on any review of the tracking and trending of objective data that identified measurable concerns or issues that were high frequency or high acuity, and was limited primarily to reporting requirements defined by the regulatory or the accrediting agencies.

Review of requested documents revealed on-going data collection of specific indicators and quality improvement projects. An interview was conducted with the Senior Director of Care Coordination and the Manager of Case Management on 1/11/2019 at 5:00 pm. The interview revealed there is no set timeframe for reporting to the Board Quality and Patient Safety committee but identified concerns would be shared with the quality council.

Review of the Quality and Patient Safety Dashboard revealed data displayed for readmissions within 7 days. November 2018 was

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A 843	Continued From page 44 the most recent month for which data was reported, along with year-to-date statistics. Review of the Patient Safety and Quality Council Meeting Minutes, dated 12/12/2018, included documentation a comprehensive dashboard review was presented to the Council. The area designated to indicate Action Plan Responsibilities and Time Frames next to the minutes of the presentation was blank.	A 843		
A 886	OPO AGREEMENT CFR(s): 482.45(a)(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose; This STANDARD is not met as evidenced by: Based on review of facility documents and staff interview it was determined the facility failed to ensure that the organ, tissue and eye donation program was integrated into the hospital's QAPI (Quality Assurance Performance Improvement) as stated and agreed upon in the OPO (Organ Procurement Organization) agreement. Findings include:	A 886		

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A 886	Continued From page 45 Review of the facility's current written agreement with the OPO, signed with the most recent addendum on 1/23/2018, revealed section G. Activity Data Review, Reporting and Quality Assessment (QA) and Improvement (QI) stated "G.1 At least annually, the Foundation shall provide Donor Hospital specific data with the appropriate Donor Hospital personnel for the purposes of quality assessment (QA) and improvement (QI), process evaluation, and to analyze outcomes of potential referral/donor situations, allowing for a collaborative plan of corrective action when indicated." Review of the facility's Board Quality and Patient Safety Committee meeting minutes revealed the last meeting in which specific data was provided was 1/19/2017. Review of requested documentation revealed the OPO provided data for calendar years 2017 and 2018. There was no evidence the data was provided to the facility's Board Quality and Patient Safety Committee for integration into the hospital's QAPI program. Interview with Physician Chief of Critical Care Medicine on 1/11/18 at 3:00 pm confirmed the OPO provided data for calendar years 2017 and 2018 with no evidence the data was provided to the facility's Board Quality and Patient Safety committee, at least annually, for integration into the hospital's QAPI program.	A 886		
A 945	SURGICAL PRIVILEGES CFR(s): 482.51(a)(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of	A 945		

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A 945	Continued From page 46 practitioners specifying the surgical privileges of each practitioner. This STANDARD is not met as evidenced by: Based on document review and staff interview it was determined the facility failed to ensure Medical Staff Bylaws were followed for determination of surgical privileges and competencies of practitioners for one (Physician A) of two active cardiovascular surgeons of fourteen practitioner's reviewed. Findings included: Review of the facility's Medical Staff Bylaws revealed each Department and Division shall develop criteria for the granting of Clinical Privileges designed to assure the Medical Staff and the Board that patients will receive quality and safe care. The criteria shall at least pertain to evidence of relevant training or experience, current competence and ability to perform the privileges requested (page 18, section 6.5). Review of the facility document, "Cardiovascular Surgery Delineation of Privileges," published 5/4/2017, stated the evidence necessary to satisfy the requirements of Clinical Experience for reappointment to the medical staff with privileges in cardiovascular surgery was evidence of 100 open cases per 2 year cycle. Review of the credentialing file for Physician A included a list of 244 surgical cases with the date and description of the procedure provided by another acute care facility located in another city. The document did not indicate whether Physician A was the primary surgeon or the assistant surgeon for the listed cases.	A 945		

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A 945	Continued From page 47 The facility did not provide any further evidence of any objective measurement for the current competency and ability to perform the requested privileges, such as outcomes analysis or morbidity and mortality statistics, for the 244 surgical procedures performed at another acute care facility which was submitted to satisfy the re-credentialing criteria for privileges in cardiovascular surgery. Review of the Credential file for Physician A revealed the list of requested privileges was signed electronically by the physician on 12/12/2017. The list included a request to perform general thoracic surgery, vascular surgery, adult cardiac including use of cardiopulmonary bypass, pediatric cardiac including use of cardiopulmonary bypass, and neonatal cardiac including use of cardiopulmonary bypass, pediatric heart transplants, and bronchoscopy. The Acknowledgement of Applicant statement, above the physician's electronic signature, read, "I have requested only those privileges for which by education, training, current experience, and demonstrated competency I want to perform and that I wish to exercise." Check boxes next to each requested privilege and the electronic signature of the Division Chair dated 1/24/2018 indicated the Division Chair approved all requested privileges. Additional documentation revealed Physician A was granted all requested privileges and re-appointed as an active member of the medical staff for the two year period from 3/1/2018 through 2/29/2020.	A 945		

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A 945	Continued From page 48 An interview was conducted with the Interim Vice President of Medical Affairs on 1/8/2019 at the time of the review of the credential files. The Vice President confirmed the finding the established criteria for granting clinical privileges in cardiovascular surgery to members of the medical staff applying for reappointment failed to meet the standard to ensure current competence and ability to perform the requested procedures as required by the Medical Staff Bylaws. An interview was conducted with the Interim Chief Executive Officer (CEO), the Senior Vice President Patient Safety Officer, the Interim Vice President of Medical Affairs, the Senior Director of Patient Safety and Quality/Interim Patient Safety Officer, the General Counsel, the Chief Operating Officer, the Regulatory Compliance Manager, the Vice President for Quality and Risk Management Johns Hopkins and other interested parties on 1/11/2019 at 9:30 a.m. The Senior Director indicated the facility has no historical data on objective indicators of quality of medical care that has been tracked, trended, and analyzed such as unplanned returns to surgery, patient deaths, or morbidity and mortality statistics by physician. The CEO confirmed the findings.	A 945		