This report is the result of an unannounced onsite complaint investigation PA00024797 completed on October 11-14, 2016 at St. Christopher's Hospital for Children. It was determined the facility was not in compliance with the requirements of 42 CFR, Title 42, Part 482-Conditions of Participation for Hospitals.

482.12 GOVERNING BODY

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 REQUIREMENT is not met as evidenced by:

An approved Plan of Correction is not on file.

Completion Date:
Status: NO POC
Based on review of facility documents, medical records (MR) and interview with staff (EMP), it was determined that the governing body failed to assume responsibility to provide oversight and accountability by failing to ensure adverse events related to surgical procedures performed at the facility were reviewed with follow-up at the Mortality and Morbidity Meetings (A0289), failed to ensure the Quality Assurance Performance Improvement Plan provided guidance for the method and frequency of data for performance indicators selected by the facility (A0273).

Review of the facility's "2016 Quality and Patient Safety Improvement Plan," approved by the "Governing Body, April 27, 2016," revealed "The SCHC [St. Christopher's Hospital for Children] Quality and Patient Safety Improvement Plan is a description of the organizational, multidisciplinary and systematic quality and safety improvement functions designed to support the Mission, Vision and Values of St. Christopher's Hospital for Children. The purpose of the Quality and Patient
Continued from page 2

Safety Improvement Plan is to identify the organization's systematic approach to improving and sustaining high quality performance through the prioritization, design, implementation, monitoring, and analysis of improvement initiatives ...

Assignment of responsibility: Board of Governors Role in the Quality and Patient Safety: The Board of Governors of St. Christopher's Hospital for Children (SCHC) plays an integral role in the leading of the Quality and Patient Safety culture within the organization ... Establish and monitor an executable strategy for quality and patient safety improvement ... Prioritize improvement initiatives and set measurable improvement targets ... reviewing and approving the SCHC Patient Safety Plan ...

CQOEPS (Center for Quality, Operational Excellence and Patient Safety) Improvement Responsibilities ... Provide adequate data management guidance to facilitate the collection, management and analysis of data needed for improvement ... Assure the standardization of quality improvement initiatives across the organization ... Measuring and Monitoring Quality:
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<th>ID</th>
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<th>(x3) DATE SURVEY COMPLETED:</th>
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<td>A 0043</td>
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<td>10/14/2016</td>
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Quality and Patient Safety Improvement Initiative must be objective and data driven ... Data collection is systematic and is used to: a.) establish a performance baseline; b) Describe the process performance stability; c) Describe the dimensions of performance relevant to functions, processes, and outcomes."

Review of facility document " SCHC Medical Staff Rules and Regulations, reviewed and approved May 24, 2016," revealed " Section VI. Committees ... 4. A. General Requirements: each medical staff committee shall address the following: 1. Quality Patient Safety and Compliance Monitoring ... 3. Responsibilities and Management: c. refer identified issues that are outside the function of the committee to another committee, individual or other group who can address the issues appropriately ... Evaluate the quality of care provided to patients receiving surgical care ... 9. Monitor outcomes associated with care delivery in surgical services and assist in identifying opportunities for improvement ... Reporting
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<td>A 0043</td>
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Responsibilities: CQOEPS Quality Metrics:
Operative or other procedures that place a patient at risk of disability or death, all significant discrepancies between pre-operative and post-operative diagnosis, including pathological diagnosis, adverse events related to using anesthesia, surgical appropriateness, surgical site infections, unplanned returns to the Operating Room (OR)

Interview on October 12, 2016, with EMP5 confirmed the frequency and method of data collection was not indicated in the Quality assurance Performance Improvement Plan.

Interview on October 14, 2016 with EMP6 confirmed the case review that is to place in the Mortality and Morbidity meeting has not been completed.

cross reference with:
482.21(b)(3) Data Collection and Analysis
482.21(c)(2) Patient Safety, Medical errors & Adverse Events
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<tr>
<td>A 0120</td>
<td>482.13(a)(2) PATIENT RIGHTS: TIMELY REFERRAL OF GRIEVANCES</td>
<td>A 0120</td>
<td>An approved Plan of Correction is not on file.</td>
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[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.] The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

This REQUIREMENT is not met as evidenced by:
Based on review of policies and procedures, medical records (MR) and interview with staff (EMP), it was determined that the facility failed to ensure the timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization for two of 30 medical records reviewed (MR21 and MR24).

Findings include:

Review on October 13, 2016, of facility policy "Medicare Beneficiaries Appeal Rights" last reviewed, January 2013, revealed "...IV Policy: 1) Hospitals must issue the Important Message for Medicare (IM) within two (2) days of admission and must obtain the signature of the beneficiary or his or her representative. Hospitals must also deliver a copy of the signed notice to each beneficiary not more than two (2) days before the day of discharge. Follow-up notice is not required if delivery of the initial IM falls within two (2) calendar days of discharge."
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days of discharge, if the beneficiary is being transferred from one inpatient hospital setting to another inpatient hospital setting, or when a beneficiary exhausts Part A hospital days. Hospitals must retain a copy of the signed notice."

1) Review on October 13, 2016, of MR21, revealed the patient was admitted on August 19, 2016, and discharged on August 25, 2016. The patient was given the IM on August 19 and again on August 22, three days before discharge.

   Interview on October 13, 2016, at 10:30 AM, with EMP3 confirmed that the patient was not given the IM within two days before discharge.

2) Review on October 13, 2016, of MR24, revealed the patient was admitted on July 6, 2016, and discharged on July 9, 2016. The patient was given the first IM on July 6. The second IM was not given to the patient.

   Interview on October 13, 2016, at 10:30 AM, with
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<tr>
<td>A 0120</td>
<td>Continued from page 8 EMP3 confirmed that the patient was not given the second IM within two days before discharge.</td>
<td>A 0120</td>
<td>An approved Plan of Correction is not on file.</td>
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<td>A 0133</td>
<td>482.13(b)(4) PATIENT RIGHTS: ADMISSION STATUS NOTIFICATION The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital. This REQUIREMENT is not met as evidenced by:</td>
<td>A 0133</td>
<td>Completion Date: Status: NO POC Date:</td>
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<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
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Based on review of policies and procedures, medical records (MR) and interview with staff (EMP), it was determined that the facility failed to ensure the patient's right to have a family member or representative of his or her choice notified of admission to the hospital for five of 30 medical records reviewed (MR9, MR10, MR15, MR23 and MR25).

Findings include:

- Review on October 13, 2016, of facility policies failed to reveal a policy to notify the patient's family member or representative of his or her admission to the hospital.

- Review on October 13, 2016, of MR9, MR10, MR15, MR23 and MR25, revealed no documented evidence that the patient's family member or representative was notified of his or her admission to the hospital.
Interview on October 13, 2016, at 10:30 AM, with EMP1 confirmed that the facility did not have a policy to notify the patient's family member or representative of his or her admission to the hospital. Further interview with EMPB1 confirmed that MR9, MR10, MR15, MR23 and MR25 did not contain any documented evidence that the patient's family member or representative was notified of his or her admission to the hospital.

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<tr>
<td>A 0166</td>
<td>482.13(e)(4)(i) PATIENT RIGHTS: RESTRAINT OR SECLUSION</td>
<td>A 0166</td>
<td>An approved Plan of Correction is not on file.</td>
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The use of restraint or seclusion must be--
(i) in accordance with a written modification to the patient's plan of care.

This REQUIREMENT is not met as evidenced by:
Based on review of facility policies, medical records (MR) and interview with staff (EMP), it was determined the facility failed to use restraints in accordance with a written modification to the patient's plan of care in four of five restraint medical records reviewed (MR1, MR2, MR4 and MR5).

Findings include:

Review on October 13, 2016, of facility policy "Restraints: Treatment Guidelines," dated October 2012, revealed "V. Procedure: A. Methodology ... 7. When a restraint is implemented, the patient's plan of care must be modified to reflect this change ... C. Documentation ... 1 ... d. Use of restraints must be addressed in the patient's modified plan of care."

1) Review on October 12, 2016, of MR1's Nursing progress notes revealed the patient was in an enclosed bed restraint on September 21, 2016, through September 24, 2016.
Interview with EMP2 on October 12, 2016, at 11:33 AM, confirmed there was documented evidence in MR1 the patient was placed in an enclosed bed restraint on September 21, 2016, through September 24, 2016. EMP1 further confirmed there was no written modification to the patient's plan of care.

2) Review on October 13, 2016, of MR2's Nursing progress notes revealed the patient was in bilateral soft limb restraints on September 14, 2016 at 3:00 PM, through September 17, 2016.

Interview with EMP1 on October 13, 2016, at 10:25 AM, confirmed there was documented evidence in MR2 the patient was placed in restraints on September 14, 2016 at 3:00 PM, through September 17, 2016. EMP1 further confirmed there was no written modification to the patient's plan of care.

3) Review on October 13, 2016, of MR4's
Continued from page 13

physician orders and nursing progress notes revealed the patient was restrained with bilateral upper extremity soft belts on July 21, 2016.

Interview with EMP1 on October 13, 2016, at 11:45 AM, confirmed there was documented evidence in MR4 the patient was placed in restraints on July 21, 2016. EMP1 further confirmed there was no written modification to the patient's plan of care.

4) Review on October 13, 2016, of MR5's physician orders and nursing progress notes revealed the patient was restrained with bilateral upper extremity soft limbs on February 3, 2015.

Interview with EMP1 on October 13, 2016, at 12:05 PM, confirmed there was documented evidence in MR5 the patient was placed in restraints on February 3, 2015. EMP1 further confirmed there was no written modification to the patient's plan of care.
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**A 0168**

482.13(e)(5) PATIENT RIGHTS: RESTRAINT OR SECLUSION

The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

This REQUIREMENT is not met as evidenced by:

| A 0168 | An approved Plan of Correction is not on file. | Completion Date: Status: NO POC Date: |
Based on review of facility policies, medical records (MR) and interview with staff (EMP), it was determined the facility failed to use restraints in accordance with physician or other licensed independent practitioners' orders for two of five restraint medical records reviewed (MR1 and MR2).

Findings include:

Review on October 13, 2016, of facility policy "Restraints: Treatment Guidelines," dated October 2012, revealed "V. Procedure: A. Methodology ...
2. Document the physician's order for restraint on the Physician's Order Sheet for Restraint ... C. Documentation 1. Each episode of restraint use shall be documented in the patient's medical record, and shall include but not be limited to: ... b. Relevant orders for use of restraints ..."

Review on October 12, 2016, of MR1's Nursing progress notes revealed the patient was in an enclosed bed restraint on September 21, 2016,
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<td>Continued from page 16 through September 24, 2016.</td>
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Review on October 12, 2016, of MR1's Physician Orders revealed there was no physician or other licensed independent practitioner's orders for the use of the enclosed bed restraint.

Interview with EMP2 on October 12, 2016, at 11:33 AM, confirmed there was documented evidence the patient was placed in an enclosed bed restraint on September 21, 2016, through September 24, 2016. EMP1 further confirmed there was no physician or other licensed independent practitioner's orders for the use of these restraints.

Review on October 13, 2016, of MR2's Nursing progress notes revealed the patient was in bilateral soft limb restraints on September 14, 2016 at 3:00 PM, through September 17, 2016.

Review on October 13, 2016, of MR2's Physician Orders revealed there was no physician or other
A 0168  Continued from page 17  

licensed independent practitioner's orders for the use of these restraints.

Interview with EMP1 on October 13, 2016, at 10:25 AM, confirmed there was documented evidence the patient was placed in restraints on September 14, 2016 at 3:00 PM, through September 17, 2016. EMP1 further confirmed there was no physician or other licensed independent practitioner's orders for the use of these restraints.

A 0186  482.13(e)(16)(iii) PATIENT RIGHTS: RESTRAINT OR SECLUSION  

[there must be documentation in the patient's medical record of]  

A 0186  An approved Plan of Correction is not on file.
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  
STATE LICENSE NUMBER: 195601

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Alternatives or other less restrictive interventions attempted (as applicable);

This REQUIREMENT is not met as evidenced by:
Based on review of facility policies, medical records (MR) and interview with staff (EMP), it was determined the facility failed to use alternatives or other less restrictive interventions attempted prior to the use of restraints in two of five restraint medical records reviewed (MR2, and MR3)

Findings include:

Review of facility policy "Restraints: Treatment Guidelines," dated October 2012, revealed "... C. Documentation 1. Each episode of restraint use shall be documented in the patient's medical record, and shall include but not be limited to: ... b. Relevant orders for use of restraints, including least restrictive intervention ..." This policy did not address the use of alternatives prior to the use of restraints.

Review on October 13, 2016, of MR2's Nursing progress notes revealed the patient was in bilateral soft limb restraints on September 14, 2016 at 3:00 PM, through September 17, 2016.
Review on October 13, 2016, of MR2's Physician Orders revealed there was no physician or other licensed independent practitioner's orders for the use of these restraints.

Further review on October 13, 2016, of MR2 revealed no documented evidence that alternatives or other less restrictive interventions were attempted prior to the use of these restraints.

Interview with EMP1 on October 13, 2016, at 10:02 AM, confirmed there was documented evidence the patient was placed in restraints on September 14, 2016 at 3:00 PM, through September 17, 2016. EMP1 further confirmed there was no documented evidence that alternatives or other less restrictive interventions were attempted prior to the use of these restraints in MR2.

Review on October 13, 2016, of MR3's physician orders and nursing progress notes revealed the patient was restrained with bilateral upper extremity handmittens on May 19, 2016.
### Statement of Deficiencies and Plan of Correction (POC)

**Name of Provider or Supplier:** ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  
**State License Number:** 195601  
**Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Department of Health and Human Services Health Care Financing Administration)**

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Further review on October 13, 2016, of MR3 revealed no documented evidence that alternatives or other less restrictive interventions were attempted prior to the use of these restraints.

Interview with EMP1 on October 13, 2016, at 11:00 AM, confirmed there was documented evidence the patient was placed in restraints on May 19, 2016. EMP1 further confirmed there was no documented evidence that alternatives or other less restrictive interventions were attempted prior to the use of these restraints in MR3.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

**NAME OF PROVIDER OR SUPPLIER:**
ST. CHRISTOPHER’S HOSPITAL FOR CHILDREN

**STATE LICENSE NUMBER:**
195601

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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<td>An approved Plan of Correction is not on file.</td>
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| A 0216 | | | 482.13(h)(1), (h)(2) PATIENT VISITATION RIGHTS

[A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.] A hospital must meet the following requirements:

1. Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

2. Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

This REQUIREMENT is not met as evidenced by:
Based on review of policies and procedures, medical records (MR) and interview with staff (EMP), it was determined that the facility failed to document that each patient (or support person) was informed of their visitation rights for 19 of 30 medical records reviewed (MR6, MR7, MR8, MR9, MR10, MR11, MR12, MR13, MR14, MR15, MR16, MR17, MR18, MR19, MR20, MR21, MR22, MR24, and MR25).

Findings include:

Review on October 12, 2016, of facility policy "Visitation Policy" last revised December 2013, revealed "...1) Inform each patient (or support person) of his or her visitation rights, including any clinical restriction on such rights, when he or she is informed of his or her other rights under this section. 2) Inform each patient (or support person) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner..."
Continued from page 24

...(including same sex domestic partner), other family member, or a friend, and his or her right to withdraw or deny such consent at any time. 3) Inform each patient of the right to designate a support person that may include, but not be limited to, a spouse, a domestic partner (including same sex domestic partner), other family member, or a friend. This support person will be authorized to stay with the patient 24 hours a day. ...


### DEPARTMENT OF HEALTH AND HUMAN SERVICES
### HEALTH CARE FINANCING ADMINISTRATION

**ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN**

STATE LICENSE NUMBER: 195601

STREET ADDRESS, CITY, STATE, ZIP CODE: 160 EAST ERIE AVE, PHILADELPHIA, PA 19134

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

**PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:** 393307

**DATE SURVEY COMPLETED:** 10/14/2016

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<tr>
<td>A 0216</td>
<td>Continued from page 25 documentation that the patient's visitation rights were provided to the patient (or support person).</td>
<td>A 0216</td>
<td>An approved Plan of Correction is not on file.</td>
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<td>A 0273</td>
<td>482.21(a), (b)(1),(b)(2)(i), (b)(3) DATA COLLECTION &amp; ANALYSIS (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.</td>
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<td>Completion Date: Status: <strong>NO POC</strong> Date:</td>
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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**
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- **STATEMENT OF DEFICIENCIES:** Continued from page 26
- **ID PREFIX TAG:** A 0273
- **PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE):**
- **COMPLETE DATE:**

**NAME OF PROVIDER OR SUPPLIER:**
- **ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN**

**STATE LICENSE NUMBER:** 195601

**STREET ADDRESS, CITY, STATE, ZIP CODE:**
- **160 EAST ERIE AVE, PHILADELPHIA, PA 19134**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**
- **ID PREFIX TAG:** A 0273
- **STATEMENT OF DEFICIENCIES:** Continued from page 26
- **ID PREFIX TAG:** A 0273
- **PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE):**
- **COMPLETE DATE:**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**
- **ID PREFIX TAG:** A 0273
- **STATEMENT OF DEFICIENCIES:** Continued from page 26
- **ID PREFIX TAG:** A 0273
- **PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE):**
- **COMPLETE DATE:**
Continued from page 27

Based on a review of facility documents and interviews with staff (EMP), it was determined that the facility failed to establish an ongoing Quality Assessment Performance Improvement (QAPI) program that included a method and frequency of data collection for the hospital-wide quality program and failed to include the method and frequency of data collection in one of two quality indicators reviewed. (Extracorporeal Membrane Oxygenation Performance Improvement).

Findings include:

Review of the facility's "2016 Quality and Patient Safety Improvement Plan," approved by the "Governing Body, April 27, 2016," revealed "The SCHC [St. Christopher's Hospital for Children] Quality and Patient Safety Improvement Plan is a description of the organizational, multidisciplinary and systematic quality and safety improvement functions designed to support the Mission, Vision and Values of St. Christopher's Hospital for Children. The purpose of the Quality and Patient

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<tr>
<td>A 0273</td>
<td>Continued from page 28 Safety Improvement Plan is to identify the organization's systematic approach to improving and sustaining high quality performance through the prioritization, design, implementation, monitoring, and analysis of improvement initiatives ... Assignment of responsibility: Board of Governors Role in the Quality and Patient Safety: The Board of Governors of St. Christopher's Hospital for Children (SCHC) plays an integral role in the leading of the Quality and Patient Safety culture within the organization ... Establish and monitor an executable strategy for quality and patient safety improvement ... Prioritize improvement initiatives and set measureable improvement targets ... reviewing and approving the SCHC Patient Safety Plan ... CQOEPS (Center for Quality, Operational Excellence and Patient Safety) Improvement Responsibilities ... Provide adequate data management guidance to facilitate the collection, management and analysis of data needed for improvement ... Assure the standardization of quality improvement initiatives across the organization ... Measuring and Monitoring Quality:</td>
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### Quality and Patient Safety Improvement Initiative

Quality and Patient Safety Improvement Initiative must be objective and data driven. Data collection is systematic and is used to:
1. Establish a performance baseline;
2. Describe the process performance stability;
3. Describe the dimensions of performance relevant to functions, processes, and outcomes.

Review on October 13, 2016, of the facility document "2016 Quality and Patient Safety Improvement Plan, approved April 27, 2016," revealed no provisions for the methodology of data collection and the frequency of data collection for facility-wide and department Performance Improvement indicators.

Review on September 13, 2016, of the performance improvement indicators for the ECMO program revealed "Quality Management Plan 2016-7 (since September 2016) Data Collection for 2016. Data collection: 1. Number of days of narcotic use after ECMO; 2. Presence and length of identified abstinence syndrome; 3. MRI’s done
### State License Number: 195601

**State Address, City, State, Zip Code:**
160 East Erie Ave, Philadelphia, PA 19134

**Name of Provider or Supplier:**
St. Christopher's Hospital for Children

**Provider/Supplier/CLIA Identification Number:**
393307

**Date Survey Completed:**
10/14/2016

**State of Health and Human Services Health Care Financing Administration**

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<td>A 0273</td>
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<td>at discharge for neonatal ECMO patients. Further review revealed no documented evidence for the frequency and method of data collection for the indicators. Interview on October 13, 2016, at 2:40 PM with EMP9 confirmed the provision for the frequency and method of data collection was not indicated in the hospital-wide Quality Plan or the ECMO performance improvement indicators. Cross reference with: 482.12 Condition of Participation: Governing Body</td>
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### A 0286

**482.21(a), (c)(2), (e)(3) PATIENT SAFETY**

(a) Standard: Program Scope
(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors.

(2) The hospital must measure, analyze, and track ... adverse patient events ...

(c) Program Activities .....  
(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: ...

(3) That clear expectations for safety are established.

This REQUIREMENT is not met as evidenced by:

An approved Plan of Correction is not on file.

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<td>Completion Date:</td>
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<td>Status: NO POC</td>
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Based on review medical records (MR), facility documents and interview with staff (EMP), it was determined that the facility failed to adequately analyze and follow-up adverse events related to surgical procedures performed at the facility for four of four medical records reviewed (MR27, MR28, MR29, MR30).

Findings include:

Review on October 12, 2016, of facility's "2016 Quality and Patient Safety Improvement Plan," approved by the "Quality Improvement Committee"April 27, 2016, revealed "... 2016 Quality and Patient Safety Improvement Plan, St. Christopher's Hospital for Children (SCHC) is committed to improving the safety and quality of care and services for the patients and communities it serves ... Assignment of Responsibility: Board of Governors Role in Quality and Patient Safety: The Board has the responsibility of overseeing progress toward achieving organization-wide goals for quality
and patient safety ... Medical Executive Committee (MEC) Role in Quality and Patient Safety: The Medical Staff Executive Committee of SCHC receives, analyzes and acts on quality and safety improvement findings ... CQOEPS Quality Improvement Responsibilities: CQOEPS is made up of hospital and medical staff representation and is responsible for maintaining the quality vision of the organization ... receive and review reports from MEC Committees, hospital committees, clinical service lines and departments ... Critically analyze reports received, recommend actions and ensure follow-up until satisfactory conclusion is achieved.

Review of facility document "SCHC Medical Staff Rules and Regulations, reviewed and approved May 24, 2016," revealed "Section VI. Committees ... 4. A. General Requirements: each medical staff committee shall address the following: 1. Quality Patient Safety and Compliance Monitoring ... 3. Responsibilities and Management: c. refer identified issues that are outside the function of the committee

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A 0286 Continued from page 34

to another committee, individual or other group who can address the issues appropriately ... M. Surgical Care Evaluation Committee: Description: Assure the quality of care for surgical patients through the development of policy and procedures, quality improvement programs ... Committee Responsibilities: 2. Evaluate the quality of care provided to patients receiving surgical care ... 9. Monitor outcomes associated with care delivery in surgical services and assist in identifying opportunities for improvement ... Reporting Responsibilities: CQOEPS Quality Metrics: Operative or other procedures that place a patient at risk of disability or death, all significant discrepancies between pre-operative and post-operative diagnosis, including pathological diagnosis, adverse events related to using anesthesia, surgical appropriateness, surgical site infections, unplanned returns to the Operating Room (OR) ... "

Review on October 12, 2016, of the "Department of Surgery Meeting Minutes, dated July 25, 2016," revealed the patient in MR27 experienced an
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<td>A 0286</td>
<td>Continued from page 35 adverse advent related to a surgical procedure performed at the facility. A request was made on October 13, 2016, for documentation regarding the outcome of the review. None was provided.</td>
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<td>Review on October 12, 2016, of the &quot;Department of Surgery Meeting Minutes, dated July 25, 2016, &quot;revealed the patient in MR28 experienced an adverse event related to pre-surgical management for a procedure performed at the facility. A request was made on October 13, 2016, for documentation regarding the outcome of the review. None was provided.</td>
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<td>Review on October 12, 2016, of the &quot;Department of Surgery Meeting Minutes, dated July 25, 2016, revealed the patient in MR29 was transferred to the facility for further treatment and expired. Review of facility documents revealed MR29 case was reviewed and referred to another hospital department, Radiology, for further case review. A request was made on October 13, 2016, for documentation regarding the outcome of the review</td>
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that was to be completed by the Radiology Department. None was provided.

Review on October 12, 2016, of the "Department of Surgery Meeting Minutes, dated August 22, 2016, revealed the patient in MR30 experienced an adverse event related to a procedure that was performed at the facility. Review of facility documents revealed MR30 case was reviewed and referred to another hospital department, ID (Infectious Diseases) and Infection control, for further case review. A request was made on October 13, 2016, for documentation regarding the outcome of the reviews that was to be completed by ID and Infection Control departments. None was provided.

Interview on October 12, 2016, at 11:50 AM, with EMP5 confirmed there was no documented evidence regarding the outcome of reviews for adverse events presented at the Mortality and Morbidity Meeting.
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<td>Cross reference with: 482.12 Condition of Participation: Governing Body</td>
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### Statement of Deficiencies and Plan of Correction (POC)

**Name of Provider or Supplier:** ST. CHRISTOPHER’S HOSPITAL FOR CHILDREN  
**State License Number:** 195601  
**Address:** 160 EAST ERIE AVE, PHILADELPHIA, PA 19134  
**Identification Number:** 393307  
**Survey Completed Date:** 10/14/2016

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<td>INITIAL COMMENT</td>
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<td>P 0147</td>
<td>101.111 CORRECTION OF DEFICIENCY</td>
<td>P 0147</td>
<td>An approved Plan of Correction is not on file.</td>
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This report is the result of an unannounced onsite complaint investigation CHL16CBRIN completed on October 11-14, 2016, at St. Christopher's Hospital for Children. It was determined that the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Hospitals, 28 PA Code, Part IV, Subparts A and B, November 1987, as amended June 1998.

Whenever any hospital notifies the Department that it has completed a plan of correction and corrected its deficiencies, the Department will conduct a survey to ascertain completion of the plan of correction. Upon finding full or substantial compliance, as defined in 101.92(b), the Department may issue a regular...
## STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

**NAME OF PROVIDER OR SUPPLIER:** ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  
**STATE LICENSE NUMBER:** 195601

**STATEMENT OF DEFIENCIES AND PLAN OF CORRECTION (POC)**

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This REGULATION is not met as evidenced by:

Continued from page 1

license.

This REGULATION is not met as evidenced by:
Based on an unannounced Federal complaint survey completed October 11-14, 2016, review of the facility's Plan of Correction (PoC for W1E811), of documents provided by the facility and staff interview (EMP), it was determined St. Christopher's Hospital for Children failed to correct deficient practice.

Findings include:

Review of 482.21(a),(b)(1),(b)(2)(i),(b)(3) Data Collection & Analysis revealed the facility continued to be out of compliance with this regulation. The deficient practice was identified during an unannounced on-site Federal complaint investigation conducted on March 16-18, 2016. The final anticipated completion date for the PoC was May 17, 2016.

1. The PoC stated "The Director of Quality or qualified designee worked with each department director or Chair to develop and implement defined metrics ... Each Department Chair, section Chief or
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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Director and staff define data collection methods and metrics were reviewed and approved by the hospital's quality and safety team ... takes responsibility to confirm that service line's define metrics, determining goals and track and trend data ... Training: the quality and patient safety met with the department chairs to assist in the selection of department metrics, and define the data collection methods for those metrics ...

Review on October 11, 2016, of the facility's "2016 Quality and Patient Safety Improvement Plan, approved April 27, 2016," revealed no provision for the methodology and frequency of facility wide data collection.

Review on October 13, 2016, of the facility's performance improvement metrics for Extracorporeal Membrane Oxygenation (ECMO) for September 2016 revealed, no provision for the methodology or frequency of collection of data.

Interview on October 14, 2016, at 2:40 PM with
EMP9 confirmed the performance improvement indicators for the ECMO did not provide a frequency or method of data collection.

Review of 482.2(c) Program Activities revealed the facility continued to be out of compliance with this regulation. The deficient practice was identified during an unannounced on-site Federal complaint investigation conducted on March 16-18, 2016. The final anticipated completion date for the PoC was May 17, 2016.

2. The PoC stated "The Department Chair or Medical Director is responsible for ensuring the Section Chiefs conduct Morbidity and Mortality reviews per the revised Rules and Regulations ... When a Section Chief identifies during case review that information is needed from another department, a copy of the request will be sent to the Quality Department ... In the event an adverse event or
A request was made on October 12, 2016, at 11:40 AM to EMP5 for the documents related to the continuing investigation and outcome of these patients. None provided.

Continuing deficiency from
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

**NAME OF PROVIDER OR SUPPLIER:** St. Christopher's Hospital for Children  
**STATE LICENSE NUMBER:** 195601  
**STREET ADDRESS, CITY, STATE, ZIP CODE:** 160 East Erie Ave, Philadelphia, PA 19134  
**ID PREFIX  TAG:** 393307  
**DATE SURVEY COMPLETED:** 10/14/2016

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103.36 (b)(2) PERSONNEL RECORDS

103.36(b)  
(2) Current information relative to periodic work performance evaluations.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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Based on review of facility policy, personnel files (PF), and staff interview (EMP), it was determined the facility failed to ensure periodic work performance evaluations were completed for one of three personnel files reviewed (PF1).

Findings include:

Review of facility policy "Performance Evaluation" last revised June 2011, revealed, "...Procedure 1. Employee will receive a written performance evaluation at the end of the initial employment period and annually thereafter. The performance evaluation is considered late if it is given 90 days after the annual due date. II. Employees who transfer to SCHC from another Tenet facility will receive a written performance evaluation at the end of the initial employment period (90 days) and annually thereafter. ..."

Review of PF1 on October 11, 2016, revealed the employee was hired on October 16, 2015. There

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was no 90 day evaluation in the personnel file.

Interview with EMP10 on October 11, 2016, at 12:15 PM confirmed that PF1 did not contain a 90 day evaluation.

P 0938  109.52 (b) ORIENTATION AND CONTINUING EDUCATION

109.52
(b) The scope and duration of the education program shall be such as to effectively train new and existing personnel. An orientation program shall be provided for each new nursing service employe.

This REGULATION is not met as evidenced by:

An approved Plan of Correction is not on file.

Completion Date:
Status: NO POC
Date:
Based on review of policies and procedures, and facility documents, and interviews with staff (EMP), it was determined the facility failed to follow its own established policy regarding the initial and continuing education of nurses who were providing ECMO [Extra Corporeal Membrane Oxygen] nursing services in five of five personnel files (PF) reviewed (PF2, PF6, PF7, PF8, and PF9).

Review on October 14, 2016, of facility policy, "Subject: ECMO Specialist Protocol Title: ECMO Training and Continuing Competency Evaluation", dated January 1, 2016, revealed "III. Desired Outcome: ... B. Training 1. Forty hours of didactic lectures to include, but not limited to physiology of diseases treated with ECMO, indications for ECMO, coagulation and anticoagulation, VA [Venous to Arterial] and VV [Venous to Venous] ECMO, ECMO equipment, emergencies and complications on ECMO, patient and circuit management, weaning from ECMO, and patient outcome ... 5. Upon completion of all training sessions, a written examination with a score of 80%
or greater ... IV. Continuing Education and Competency Assessment Evaluation Competency maintenance and evaluation will be assessed quarterly unless an ECMO patient run voids the wet drill practice session ..."

Review on October 14, 2016, of PF2 revealed there was no documented evidence that this employee completed the required 40 hours of didactic lectures. Further review revealed no documented evidence this employee received an 80% or greater on the written examination [there was no written examination].

Review on October 14, 2016, of PF6 revealed there was no documented evidence that this employee completed the required 40 hours of didactic lectures. Further review revealed no documented evidence this employee received an 80% or greater on the written examination [there was no written examination]. The last quarterly drill this employee participated in was April 2016. There was no drill for the third quarter of 2016.
Review on October 14, 2016, of PF7 revealed there was no documented evidence that this employee completed the required 40 hours of didactic lectures. Further review revealed no documented evidence this employee received an 80% or greater on the written examination [there was no written examination]. The last quarterly drills this employee participated in was November 2015 and August 2016. This employee did not participate in quarterly drills for the first and second quarters of 2016.

Review on October 14, 2016, of PF8 revealed there was no documented evidence that this employee completed the required 40 hours of didactic lectures. Further review revealed no documented evidence this employee received an 80% or greater on the written examination [there was no written examination]. The last quarterly drills this employee participated in was April 2015 and August 2016. There was no drills for the second and third quarters of 2015, and first and...
second quarters of 2016.

Review on October 14, 2016, of PF9 revealed there was no documented evidence that this employee completed the required 40 hours of didactic lectures. Further review revealed no documented evidence this employee received an 80% or greater on the written examination [there was no written examination]. The last quarterly drills this employee participated in was April 2016 and August 2016. There was no drills for the first quarter of 2016.

Interview with EMP3 on October 14, 2106, at 1:05 PM confirmed the above findings.