This report is the result of an unannounced Federal investigation conducted onsite on October 29, 2015, at St. Christopher's Hospital for Children and completed off-site on March 9, 2016. It was determined that the facility was not in compliance with the requirements of 42 CFR, Title 42, Part 482-Conditions of Participation for Hospitals.

Any deficiency statement ending with an asterisk (*) denotes a deficiency which may be excused from correction providing it is determined that other safeguards provide sufficient protection to the patients. The findings stated above are disclosable whether or not a plan of correction is provided. The findings are disclosable within 14 days after such information is made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

This form is a printed electronic version of the CMS 2567L. It contains all the information found on the standard document in much the same form. This electronic form once printed and signed by the facility administrator and appropriately posted will satisfy the CMS requirement to post survey information found on the CMS 2567L.
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NAME OF PROVIDER OR SUPPLIER: ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN | STREET ADDRESS, CITY, STATE, ZIP CODE: 160 EAST ERIE AVE PHILADELPHIA, PA 19134 | PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307 | DATE SURVEY COMPLETED: 03/09/2016 |
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<td>482.13 PATIENT RIGHTS</td>
<td>The plan of correction is prepared in compliance with federal regulations and is intended as St. Christopher's Hospital for Children (the &quot;hospital&quot;) credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.</td>
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<td>A hospital must protect and promote each patient's rights.</td>
<td>Organization Minutes: The confidential and privileged minutes are being retained at the facility for agency review and verification if required.</td>
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<td>This REQUIREMENT is not met as evidenced by:</td>
<td>Response: Hospital leadership and staff are committed to delivering safe care to our patients and to improving the quality of care by promoting evidence based best practices that improve patient safety, reduce risk, and prevent adverse events consequential to the course of medical treatment. The hospital has an ongoing effort to identify patient safety issues, continuously review the care provided to our patients and develop plans to reduce errors and improve care. Hospital leadership</td>
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### Statement of Deficiencies and Plan of Correction (POC)

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and staff review events daily and action plans are developed as relevant to the event. There is a focus on catching "near miss/hits" that never reach the patient. Aggregate event data is reviewed by the Quality and Patient Safety Department for further development of action plans to enhance patient safety.

Tag: A 115

Policy & Procedures:
The Chief Nursing Officer, the Risk Manager and the Director Clinical Quality Improvement reviewed the policies on 20.60 Patient Rights and Responsibilities 30.23 Medication Management Plan for St. Christopher's Hospital for Children 30.52 Monitoring the Effects of Medication on Patients and the 2016 Patient Safety Plan to ensure they meet current standards of care and practice. No revisions were required to the current policies. The Director of Admissions reviewed and revised the Admission policy and procedure to state that...
the Admissions department will fax the notification of Admission to the patient's primary care physician within 24 hours of the patient's admission to the hospital.

Training:
The Director of Admissions educated the Admissions staff on the revised process to notify the patient's primary care physician on admission to the hospital.
The Director of Professional Development and the Chief Nursing Officer will include Medication Safety as a focus during the nursing annual competencies.

Monitoring: The Director of Admissions or designee will review the Admission log daily for documentation that the Admissions staff has completed notification to the primary care provider that their patient has been admitted to the hospital. Any identified discrepancies will be rectified immediately. The Director of Admissions will conduct a random review of 70 records quarterly for documentation of the primary care
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<td>physician notification. The results of this audit will be presented quarterly to the hospital's Quality and Patient Safety committee for review and action as required. Responsible Person(s): Director of Admissions; Chief Financial Officer; Director Clinical Quality Improvement; Director of Risk Management; Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.</td>
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Based on review of medical records (MR), review of facility documents and interview with staff (EMP) it was determined that the facility failed to protect and promote each patient's right as evidence by: failing to ensure that the patient had a right to have their primary care physician notified of their admission to the hospital (A0133); and failing to implement and adhere to safety measures during the administration of medication to ensure a patient's safety and well being (A0144).

Cross Reference:
482.12(b)(4) Patient Rights: Admission Status Notification
482.13(c)(2) Patient Rights: Care in Safe Setting
482.23(b)(5) Patient Care Assignments
482.23(c)(1),(c)(1)(i) &c(c)(2) Administration of Drugs
482.25(a)(2) Pharmacy Personnel
482.25(b) Delivery of Drugs
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| A         | 0133 | ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN                | 160 EAST ERIE AVE
Philadelphia, PA 19134                                                          |
|           |      | PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307   | ID PREFIX  TAG: A 0133                                                         |
### 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:

#### Tag: A133

Policy and Procedures:
The Director of Admissions reviewed and revised the Admission policy and procedure to state that the Admissions department will fax the notification of Admission to the patient's primary care physician within 24 hours of the patient's admission to the hospital.

Training:
The Director of Admissions educated the Admissions staff on the revised process to notify the patient's primary care physician on admission to the hospital.

Monitoring:
The Director of Admissions or designee will review the Admission log daily for documentation that the Admissions staff has completed notification to the primary care provider that their patient has been admitted to the hospital. Any identified discrepancies will be rectified immediately. The Director of Admissions will conduct a random review of 70 records quarterly for documentation of the primary care
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<td>physician notification. The results of this audit will be presented quarterly to the hospital's Quality and Patient Safety committee for review and action as required. Responsible Person(s): Director of Admissions Chief Financial Officer Director Clinical Quality Improvement Director of Risk Management Quality and Patient Safety Committee Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures</td>
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Based on review of medical records (MR), review of facility policies and interview with staff (EMP), it was determined that the facility failed to ensure the patient's right to have the primary care provider (PCP) notified of admission to the hospital for nine of 11 of medical records reviewed (MR1, MR4, MR5, MR6, MR7, MR8, MR9, MR10 and MR11).

Findings include:

Review on October 29, 2015, of facility policies failed to reveal a policy regarding the notification of a patient's PCP upon the patient's admission to the hospital.

Review on October 29, 2015, of MR1, MR4, MR5, MR6, MR7, MR8, MR9, MR10 and MR11 revealed no documented evidence that the patient's PCP was notified of the patient's admission to the hospital.

Interview on October 29, 2015, at 11:15 AM, with
EMP6 confirmed that the facility did not have a policy to notify the patient's PCP upon admission to the hospital. Further interview with EMP6 confirmed that MR1, MR4, MR5, MR6, MR7, MR8, MR9, MR10 and MR11 did not contain any documented evidence that the patient's PCP was notified upon admission.
482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING

The patient has the right to receive care in a safe setting.

This REQUIREMENT is not met as evidenced by:

**Policy & Procedures:**
The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:

- Conduct a physician to physician or a physician to CRNP accuracy check prior to orders being written and sent to the pharmacy.
- The Pharmacy staff will:
  - Use a double checks process for the custom road map for each individual patient.
  - Have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map.
  - Use the revised Antineoplastic Drug Profile check list to document the verification process for orders.
  - Document the independent double check completed by pharmacy staff and:
  - Complete a record of who prepared the chemotherapy and who...
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<td>completed the double check of the chemotherapy that has been prepared.</td>
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<td>X all pharmacists who are assigned to prepare chemotherapy will receive</td>
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<td>training and education and complete a chemotherapy certification class.</td>
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<td>The Nursing Staff will „ X require two chemotherapy certified (APHON)</td>
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<td>nurses to complete the double check process and document it so that a</td>
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<td>certified chemotherapy nurse may administer the chemotherapy.</td>
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<td>The revised policy was reviewed and approved at the Pharmacy and</td>
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<td>Therapeutics Committee on April 11, 2016.</td>
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<td>Training:</td>
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<td>The Director of Pharmacy or qualified designee educated all medical,</td>
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<td>pharmacy and nursing staff on the revised policy related to</td>
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<td>Chemotherapy and Hazardous Medication Management. This information has</td>
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<td>been included in new pharmacy and nursing employee education and annual</td>
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<td>re-orientation. Any physician who</td>
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<td>writes orders for chemotherapy will receive education on the policy as part of onboarding to the medical staff. The Chief Nursing Officer and the Director of Professional Development will offer a Chemotherapy Certification course to the nursing department to add additional nursing staff who will be chemotherapy certified. (APHON) Monitoring: The Director of Clinical Quality Improvement, the Director of Pharmacy or designee will monitor 100% of chemotherapy patient records concurrently for completion of the road map double checks, pharmacy verification process and nursing double check administration process. The monitoring will continue until there is 100% compliance for 4 consecutive months. The monitoring will also include a review of the chemotherapy that is prepared and administered so ensure that only chemotherapy certified RN's administer chemotherapy and only</td>
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<td>chemotherapy trained pharmacists prepare/dispense chemotherapy. The information from monitoring will be reported to the hospital's Quality and Patient Safety Committee on a quarterly basis; and to the Medical Executive Committee and the Governing Board quarterly for review and action as required. Responsible Person(s): Pediatrician-in-chief; Section Chief of Oncology Chief Nursing Officer; Director of Pharmacy Director Clinical Quality Improvement Quality and Patient Safety Committee Medical Executive Committee Governing Board Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. Medical Staff members</td>
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Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to implement and adhere to safety measures during the administration of medications to ensure a patient's safety and well-being for one of one medical record reviewed (MR1).

Findings include:

1. Review of facility policy "Rights and Responsibilities of Patients," dated January 14, 2014, revealed "I) Policy: 1) St. Christopher's Hospital for Children is committed to providing the best possible care to children and youth in a family-centered environment. ... II) Patient Rights: Patients and/or parents or guardians acting on behalf of the patient have a right: ... 3) To provide considerate, respectful care given by competent personnel, including consideration of the psychosocial, spiritual and cultural variables that influence perception of illness. ... 18) To good
Continued from page 18

quality care and high professional standards that are continually maintained and reviewed. ...25) To expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient and family. The patient and the family have the right to expect reasonable safety insofar as hospital practices ..."

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of
cancer. Review of the "Roadmap" revealed " ... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication] 1800 mg m2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr Cl, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m2/day (33 mg/kg if age <1 yr) days 1-5. ..." The "Roadmap" revealed the following handwritten calculation for Etoposide " ... 280 mg ..." Further review of the "Roadmap" revealed that the document was not dated, nor was it authenticated by the individual who transcribed the "Roadmap" and performed the calculations that were contained on the "Roadmap."

Review of MR1 "Physicians' Orders," dated October 1, 2015, revealed " ... Etoposide (33 mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hours at 50 cc/hr. Repeat 5 days. ..."

Review of MR1 "Medication Administration," dated
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October 2, 2015, timed: 00:52, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP19] 10/02/2015 00:52; Verify: [EMP18] ...."

Review of MR1 "Nursing/Clinical Info," dated October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results wnl to begin chemo. 2315: Loading dose of zoferan given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosfamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn given (abx compatible with Mesna per pharmacy).
Mesna boluses to be given hrs 3, 9, 12. [patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor."

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP20] 10/03/2015 00:53; Verify: [EMP 18] ... ."

Review of MR1 "Nursing/Clinical Info," dated October 3, 2015, performed at 06:59, by EMP18 revealed "... 01:00: Etoposide given over 2 hrs via left chest port. ... Pt. tolerate well and no adverse reactions noted. ..."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ... ."
Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] .... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 5, 2015.

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP23] 10/04/2015 00:55; Verify: [EMP18] .... ."

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed "...01:00: Etoposide given over 2 hours via
right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ..."

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

**NAME OF PROVIDER OR SUPPLIER:** ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  
**STATE LICENSE NUMBER:** 195601  
**STATE STREET ADDRESS, CITY, STATE, ZIP CODE:** 160 EAST ERIE AVE, PHILADELPHIA, PA 19134

### Multiple Construction:

A. **BLDG:** 00  
B. **WING:**

### Completed Date Survey

**DATE SURVEY COMPLETED:** 03/09/2016

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10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed "... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ... RESIDENT A/P Assessment: ... After discovering the incorrect Etoposide dose, [the patient] was closely monitored. ... Patient is being closely monitored for possible liver, renal, bone marrow, neurologic, and respiratory damage secondary to potential Etoposide toxicity. Plan:
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

DATE SURVEY COMPLETED: 03/09/2016

ID PREFIX  TAG: A 0144

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

Oncology: Completed chemotherapy 10/6 ... patient awaiting transfer to [another health care facility] on 10/6/2015. ...

Review of MR1 revealed no documentation pertaining to the two medication precipitating events that occurred prior to October 6, 2015. Further review of MR1 revealed no documented evidence that the physician was notified and assessed the patient during the two previous medication precipitating events that occurred prior to October 6, 2015. There was no documented evidence that pharmacy was notified of the two previous medication events that occurred prior to October 6, 2015.

Interview on January 11, 2016, at 10:00 AM, with EMP1 and EMP10 revealed that on October 6, 2015, EMP11, reviewed the dosing and concentration of Etoposide after being notified by EMP18 that the medication had precipitated during administration; EMP11 identified that the concentration/dose was too high.
### Interview on January 11, 2016, at 10:20 AM

EMP1 indicated that a root cause analysis (RCA) was performed. EMP1 revealed that they didn't know why it took the facility five days to realize that there was an error with the dosage of Etoposide that was being provided to the patient in MR1. EMP1 indicated that the event was due to a "typographical" error made by EMP13. EMP1 indicated that four oncologists, EMP13, EMP14, EMP15 and EMP16, created the custom "Roadmap" to treat the patient's illness. EMP1 indicated that "the dose was to be 3.3 [mg/kg] not 33 [mg/kg] but EMP13 wrote down '33' instead of '3.3'" and then EMP17 transcribed the order based on what was written on the "Roadmap."

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 revealed that a medication can precipitate if the concentration is too high or if there...
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<td>is not enough diluent. EMP1 confirmed that nursing is aware of what can cause a medication to precipitate. EMP1 confirmed that nursing did not document this event in the patient's medical record and revealed that nursing &quot;documents by exception&quot; meaning that &quot;they document unusual occurrences.&quot; EMP1 confirmed that this event, involving the first occurrence of the Etoposide precipitating, was not reported to the Department or the Patient Safety Authority. At 10:59 AM EMP1 confirmed that there was no documented evidence that the physician and/or pharmacy was notified of this event. EMP1 indicated that &quot;most of the medication was administered by the time it was realized.&quot; Review of MR1 revealed no documented evidence regarding the exact amount of medication that the patient received during the first precipitating event that occurred on October 2, 2015 or the second precipitating event that occurred on October 4, 2015.</td>
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<td>2. Review of facility policy &quot;High Risk Medications Management (High Alert),&quot; dated March 2014,</td>
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revealed "I. Policy SCHC will develop and maintain a list of High Risk Medications. Medications and medication classes on this list will be subject to greater control due to the high potential for errors or consequences of errors. II. Purpose To outline processes for defining, communicating, and enforcing medication management safety measures to promote safe use of high alert high risk medications and reduce medication errors and their consequences. III. Procedure A. Definitions 1. High risk medications: Medications that bear heightened risk of causing significant patient harm when used in error (Institute for Safe Medication Practice ISMP). ... B. Processes will be in effect at every stage of medication management that relates to high risk medication use. ... 3. Prescribing/Transcribing ... c. Dose range checking is utilized in both PowerChart CPOE and PharmNet. d. When high risk medications are ordered by the provider using an alternative to CPOE, e.g., chemotherapy protocols ... , the relevant orders will be transcribed by the pharmacist into PharmNet and thus into the eMar and PowerChart. e. Down time handling of orders.
### Statement of Deficiencies and Plan of Correction (POC)

**Name of Provider or Supplier:**

**State License Number:**

**Street Address, City, State, Zip Code:**

**Date Survey Completed:**

**State of Health and Human Services**

**Health Care Financing Administration**

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<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Complete Date)</th>
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will include double check by the pharmacist of all high risk medication orders and adherence to downtime policies for nursing and providers. 4. Preparation/Dispensing  
a. Independent double check by the person who prepares the high risk medication and a second person (one of who must be a licensed pharmacist) are mandatory. ... 5. Administration  
b. Independent confirmation of the order and visual confirmation of the medication label by two licensed personnel must occur prior to administration of the medication. ... 6. Monitoring  
Medication events are reported according to the event reporting policy, ... ."  

A. Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ... these | A 0144 | | |
medications. ... Administration ... a. Chemotherapy is to be administered to the patient only by a chemo certified nurse in designated locations (... OTU, ...) ... "

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 m; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18, Witness: EMP20 10/3/2015 00:53; Verify: EMP18 ..."

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 4:03, revealed "Mesna 100 mg 1 mL; d5nsh250 150 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP20 10/03/2015 04:03; Verify: EMP18 ..."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 12:28, revealed "Mesna d5i25 25 mL; mesn1i 100 mg 1 mL IV Chemo, Infusaport ... Perform: EMP8; Witness: EMP24 10/4/2015 12:28; Verify: EMP8 ..."
Review of MR1 "Medication Administration," dated October 5, 2015, timed: 12:52, revealed "Mesna mesn1i 100 mg 1 mL; d5i25 25 mL IV Chemo, Infusaport ... Perform: EMP25; Witness: EMP26 10/5/2015 12:52; Verify: EMP25 ..."

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 00:55; Verify: EMP18 ..."

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 05:12, revealed "Ifex 500 mg+ Mesnex 100 mg ... IV Chemo, Infusaport ... Perform: EMP18 10/6/2015 03:08; Witness: EMP27 10/6/2015 03:08; Modify: EMP18 10/6/2015 05:11; Witness: EMP27 10/6/2015 05:11; Verify: EMP18 ... Result comment: EMP18 Chemo started late as port clotted and had to be reaccessed. ..."

Review of MR1 "Medication Administration," dated
October 6, 2015, timed: 04:32, revealed "Mesna ... IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 04:32; Verify: EMP18 ...
"

On January 26, 2016, at 3:33 PM, a request was submitted to EMP9 for documentation of specialized training in chemotherapy medications for the nurses who administered chemotherapy medication to the patient on October 2, 3, 4, 5, and 6.

Review of documents submitted to the Department, on January 28, 2016, at 4:36 PM, by EMP9 revealed no documented evidence that EMP20 and EMP23, who participated in the administration and verification process of the administration of chemotherapy medications, were chemotherapy certified in accordance with facility policy.

Review of correspondence submitted to the Department, on February 11, 2016, at 11:39 AM, from EMP9 revealed that the facility does not
### ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN

**STATE LICENSE NUMBER:** 195601

**STREET ADDRESS, CITY, STATE, ZIP CODE:** 160 EAST ERIE AVE

**PHILADELPHIA, PA 19134**

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"specify that the second professional must be APHON [Association of Pediatric Hematology/Oncology Nurses] Biotherapy certified."

On March 8, 2016, at 3:13 PM, another request containing a list of additional nurses who administered chemotherapy medication to the patient was submitted to EMP9.

Review of correspondence submitted to the Department, on March 9, 2016, at 12:42 PM, by EMP9, revealed that EMP24, EMP26 and EMP27, who participated in the administration and verification process of the administration of chemotherapy medications, were not chemotherapy certified in accordance with facility policy.

3. Review of facility policy "Chemotherapy and Hazardous Medication Management," dated March 2014, revealed "**1. Policy A.** Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a
medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ... these medications. ...

**II. Purpose**

Certain medications carry unique hazards. This policy promotes knowledge and understanding of these effects and how to mitigate them except as applied to patient therapy. Policy will dictate the handling of these medications in a way that promotes better patient care and safety ....

**IV. Procedure**

A. Chemotherapy ...

2. Order processing, preparation and handling

a. The pharmacist receiving the order (pharmacist #1) i. Will review the order for patient appropriateness and clarify the order with the ordering heme/onc attending when necessary. ii. Will check the pertinent laboratory data. iii. Will enter the order into the computer to generate a patient charge and a label for the drug which includes: ... k) Initials of preparer and the checker ... iv. Must retrieve the patient chemotherapy profile in the Oncology Clinic (if it exists) or create a new patient folder and profile. ...
b. Pharmacist #1 will complete the Pharmacy Drug Profile sheets for each drug in the order; Pharmacist #2 will verify the work. ... d. Each chemotherapeutic agent must be admixed individually by a pharmacy technician and all work checked by a pharmacist. i. Chemotherapeutic agents will be prepared by personnel specially trained in chemotherapy handling. ... e. Both pharmacists will retrieve and review the label, the order, and the patient profile; then review admixing instructions with the pharmacy technician utilizing package inserts and other references needed. f. Prior to having a certified chemo technician complete the preparation of products, the pharmacist will call a second pharmacist (pharmacist #2) to check the following: i. The original orders against the printed label and all calculations ii. The original orders against the protocol and roadmap (chemotherapy profile) ... g. ... vi. The preparer will affix the prepared label and precautionary labels to the final product and indicate completeness by initialing the chemotherapy profile. h. The pharmacist witnesses the technician completing the preparation, initials the label, and
initials the chemotherapy profile. ... j. The patient chemotherapy order form will be placed in the chemotherapy file for future reference. ... 4. Administration a. Chemotherapy is to be administered to the patient only by a chemo certified nurse in designated locations (... OTU, ...). If it is necessary to administer chemotherapy in non-designated areas, the administration will be done by a chemo certified nurse. ..."

Interview on January 11, 2016, at 10:13 AM, with EMP10 revealed that the "'normal chemo' pharmacist [EMP4]" was not working during the time Etoposide was prepared and dispensed to the patient in MR1. EMP10 revealed that the pharmacists who prepared and dispensed the Etoposide don't frequently prepare chemotherapy medications. EMP1 indicated that the pharmacists are not certified in chemotherapy medication preparation and that there is no facility policy that requires it. EMP1 revealed that these pharmacists "have been here for years but that they received training during orientation on pediatric dosing and..."
mixing chemotherapy medications." EMP10 revealed that as a result of the medication error, involving Etoposide, the pharmacist working in oncology will rotate as to who prepares chemotherapy medications in order to maintain competency.

On January 26, 2016, at 9:03 AM, a request was submitted to EMP9 for a list of the actual pharmacists who prepared and dispensed Etoposide on October 2, 3, 4, 5, and October 6, 2015. EMP9 was also asked for a copy of their last training/education that each pharmacist received regarding chemotherapy pharmacy.

Review of correspondence submitted to the Department, on January 28, 2016, at 4:22 PM, from EMP9 revealed that the facility did not have record as to which pharmacists actually prepared and dispensed Etoposide on October 2, 3, 4, 5 and October 6, 2015. EMP9 indicated that the pharmacist signs the label after it is printed, but then the label is discarded once the medication is
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finished. EMP9 revealed that there are no specialized educational requirements or oncology specific requirements that are required of the pharmacists in order to work in oncology. EMP9 indicated that "... pharmacists orient with [EMP4] in the oncology clinic checking and verifying orders and learning the processes involved until they feel that they can handle clinic and chemotherapy admissions. This is usually a 3 to 6 month period depending on it they have any prior experience.

There was no documented evidence that pharmacy double-checked the physician's order for Etoposide to ensure accuracy and patient appropriateness in accordance with facility policy.

4. Interview on February 4, 2016, at 9:00AM, with EMP9 revealed that EMP13 typed the "Roadmap."

Interview on February 4, 2016, at 9:09 AM, with EMP10 revealed that literature was used to develop the patient's treatment protocol, the customized
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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"Roadmap." EMP10 revealed that the literature was not included in the patient's chart nor was it sent to pharmacy to allow for pharmacy to review with the "Roadmap" prior to filling the orders. EMP10 revealed that the literature used to develop customized "Roadmaps" would "sometimes" be sent to pharmacy, "but not always." EMP10 revealed that the facility did not have an established policy for this process.

Interview on February 4, 2016, at 9:17 AM, with EMP1 revealed that standardized "Roadmaps" are "vetted and go through an IRB process" prior to implementation. EMP1 indicated that custom "Roadmaps" do not go through the same "vetting" process like the standardized "Roadmaps."

Interview on February 4, 2016, at 9:24 AM, with EMP9 confirmed that the "Roadmap" document, contained in MR1, was not dated nor was it authenticated. EMP9 indicated that the document should have been authenticated and dated.
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On February 4, 2016, the facility was asked for a policy related to oncologists reviewing and signing custom "Roadmaps" to ensure accuracy prior to sending to pharmacy, since custom "Roadmaps" are not "vetted" in the same manner. At 9:24 AM, EMP9 revealed that the facility did not have a policy.

There was no evidence that the facility had a mechanism in place to ensure the accuracy of customized "Roadmaps" that were being used to treat rare medical conditions.

5. Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional
services were rendered to the patient. ... h) All entries in a patient's medical record shall be consistent and noncontradictory; information recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ...

Review of MR1 "Oncology Daily Progress Note," dated October 2, 2015, timed 14:01, authenticated by EMP14 on October 3, 2015 at 21:00, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ...".

Review of MR1 "Physician Progress Notes," dated October 3, 2015, timed 01:11, authenticated by EMP14 at 20:59, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ...".

Review of MR1 "Physician Progress Notes," dated October 4, 2015, timed 04:03, authenticated by EMP14, revealed " ... Plan: Oncology: ... -
etoposide 280 mg x 5 days ".

Review of MR1 "Physician Progress Notes," dated October 5, 2015, timed 19:56, authenticated by EMP14, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ".

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a
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decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Interview on January 11, 2016, at 10:20 AM, with EMP1 indicated that a root cause analysis (RCA) was performed. EMP1 revealed that they didn't know why it took the facility five days to realize that there was an error with the dosage of Etoposide that was being provided to the patient in MR1. EMP1 indicated that the event was due to a "typographical" error made by EMP13. EMP1 indicated that four oncologists, EMP13, EMP14, EMP15 and EMP16, created the custom "Roadmap" to treat the patient's illness. EMP1 indicated that "the dose was to be 3.3 [mg/kg] not 33 [mg/kg] but EMP13 wrote down '33' instead of '3.3', omitting the decimal point. EMP17 then transcribed the order based on what was written on the "Roadmap."

Review of MR1 "Physician Progress Notes" revealed that EMP14, who was involved in creating the customized "Roadmap" to treat the patient's
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condition, repeatedly authenticated the incorrect dose: "etoposide 280 mg x 5 days."

The facility failed to implement and adhere to safety measures during the administration of medication to ensure a patient's safety and well-being.
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#### 482.23(b)(5) PATIENT CARE ASSIGNMENTS

A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

This REQUIREMENT is not met as evidenced by:

- **Tag:** A 0397
- **Policy & Procedures:**
  - The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure.
  - 30.16 Chemotherapy and Hazardous Medication Management to include the following:
    - Nursing will require two chemotherapy certified (APHON) nurses to complete the double check process and document it so that a certified chemotherapy nurse may administer the chemotherapy.
    - The revised policy was reviewed and approved at the Pharmacy and Therapeutics Committee on April 11, 2016.
  - **Training:**
    - The Director of Pharmacy or qualified designee educated all medical, pharmacy and nursing staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy and nursing employee education and annual re-orientation. Any physician who
A 0397 writes orders for chemotherapy will receive education on the policy as part of onboarding to the medical staff.

The Chief Nursing Officer and the Director of Professional Development will offer a Chemotherapy Certification course to the nursing department to add additional nursing staff who will be chemotherapy certified. (APHON) Monitoring:

The Director of Clinical Quality Improvement, the Director of Pharmacy or designees will monitor 100% of chemotherapy patient records concurrently for completion of the roadmap double checks, pharmacy verification process and nursing double check administration process. The monitoring will continue until there is 100% compliance for 4 consecutive months.

The information from monitoring will be reported to the hospital's Quality and Patient Safety Committee on a quarterly basis; and to the Medical Executive Committee and the
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<td>Governing Board quarterly for review and action as required. Responsible Person(s): Director of Professional Development Chief Nursing Officer; Pediatrician in Chief Director of Pharmacy Director Clinical Quality Improvement Quality and Patient Safety Committee Medical Executive Committee Governing Board Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate</td>
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Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP) it was determined that the facility failed to ensure that nursing staff participating in the administration of chemotherapy medications were chemotherapy certified in accordance with facility policy for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Infusion Medication Administration (IMAR), Last Rev [review] Date: 10/12 [2012] Next Rev Date: 12/13 [2013]," revealed "I. POLICY: An infusion medication administration record will be maintained for every high-risk medication administration as an infusion. Every infusion will require an individual record. Two RNs will participate in the verification and documentation of these infusions. ... II. PERFORMED BY: 2 Registered Nurses III. DESIRED OUTCOME: In order to ensure
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accurate verification and documentation of all high-risk infusions, two RNs will participate in the verification and documentation of all high-risk infusions. ...

Review of facility policy "Chemotherapy and Hazardous Medication Management," dated March 2014, revealed "I. Policy A. Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ... these medications. ... Administration ... a. Chemotherapy is to be administered to the patient only by a chemo certified nurse in designated locations (OTU, ...) ...

Review of facility policy "Chemotherapy Administration (Antineoplastic and Cytotoxic Drugs), dated February 2015, revealed "I. Policy During preparation for chemotherapy administration, health care personnel, the patient and the
A 0397

environment will be protected from unnecessary exposure to potentially hazardous substances. ... II. General Information A. Physician Orders: 1. ...Physician orders are required and must include the following information: protocol number, day, week, pre and post hydration orders, anti-emetics, drug, height, weight, Body Surface Area (BSA), dosage, route, diluent, administration frequency, and special precautions. ...C. Intravenous Infusion Chemotherapy: The following guidelines shall govern the administration of IV chemotherapeutic agents: ... 8. ... When using a Buretrol to administer medications, flush with appropriate agent between chemotherapy drug and medication. ... 13. Hourly assessment of peripheral and/or central venous access site is required during infusion of IV chemotherapeutic agents. During central line infusions, check dressing and chest wall every hour during chemotherapy administrations for signs of infiltration. ... 14. Hourly checks of infusion container, buretrol and pump settings should be completed and documented in the electronic record.

15. **Special nursing consideration: Etoposide**
(VP-16) and Teniposide (VM-26) require the RN to be present and monitor the administration of either of these drugs throughout the infusion ... III. PERFORMED BY: Registered Nurses: RN ' s in the Oncology Unit, Oncology Clinic, and 5 West (Oncology Unit overflow) are required to be APHON Biotherapy Certified. ... VI. PROCEDURE: A. Preparatory Phase 1. Check physician ' s order, review BSA, check the label of all chemotherapy containers for patient ' s name, date, correct medication, dosage and diluent, expiration date and bottle number prior to infusion. This step needs to be independently double checked by another licensed practitioner and documented on the MAR. ... C. Follow-Up Phase ... 3. Document chemotherapy administration in the electronic record and EMR including the following information: location and type of line, chemotherapy dose, amount infused, sequence of drugs, type of flush solution and amount, description of infusion site, pre-medications, any reactions and/or interventions, responses, and indication that orders were double-checked. a. I/O Inet: Location and type of
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<td>Continued from page 52 line, amount infused (chemotherapy), flush amount, description of infusion site, reactions and/or interventions, and responses. b. EMR: Pre-medications, chemotherapy dose, sequence of drugs, and type of flush, indication that orders were double-checked. ...</td>
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Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplain x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18, Witness: EMP20 10/3/2015 00:53; Verify: EMP18 ..."

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October 3, 2015, timed: 4:03, revealed "Mesna 100 mg 1 mL; d5nsh250 150 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP20 10/03/2015 04:03; Verify: EMP18 ..."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 12:28, revealed "Mesna d5i25 25 mL; mesn1i 100 mg 1 mL IV Chemo, Infusaport ... Perform: EMP8; Witness: EMP24 10/4/2015 12:28; Verify: EMP8 ..."

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 12:52, revealed "Mesna mesn1i 100 mg 1 mL; d5i25 25 mL IV Chemo, Infusaport ... Perform: EMP25; Witness: EMP26 10/5/2015 12:52; Verify: EMP25 ..."

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 00:55; Verify: EMP18 ..."
**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**

**DATE SURVEY COMPLETED:** 03/09/2016

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<tr>
<td>A 0397</td>
<td>Continued from page 54 Review of MR1 &quot;Medication Administration,&quot; dated October 6, 2015, timed: 05:12, revealed &quot;Ifex 500 mg+ Mesnex 100 mg ... IV Chemo, Infusaport ... Perform: EMP18 10/6/2015 03:08; Witness: EMP27 10/6/2015 05:11; Verify: EMP23 10/6/2015 04:32; Result comment: EMP18 Chemo started late as port clotted and had to be reaccessed. ...&quot;</td>
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Review of MR1 "Medication Administration," dated October 6, 2015, timed: 04:32, revealed "Mesna ... IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 04:32; Verify: EMP18 ...

On January 26, 2016, at 3:33 PM, a request was submitted to EMP9 for documentation of specialized training in chemotherapy medications for the nurses who administered chemotherapy medication to the patient on October 2, 3, 4, 5, and 6.
Review of documents submitted to the Department, on January 28, 2016, at 4:36 PM, by EMP9 revealed no documented evidence that EMP20 and EMP23, who participated in the administration and verification process of the administration of chemotherapy medications, were chemotherapy certified in accordance with facility policy.

Review of correspondence submitted to the Department, on February 11, 2016, at 11:39 AM, from EMP9 revealed that the facility does not "specify that the second professional must be APHON [Association of Pediatric Hematology/Oncology Nurses] Biotherapy certified."

On March 8, 2016, at 3:13 PM, another request containing a list of additional nurses who administered chemotherapy medication to the patient was submitted to EMP9.

Review of correspondence submitted to the Department, on March 9, 2016, at 12:42 PM, by
EMP9, revealed that EMP24, EMP26 and EMP27, who participated in the administration and verification process of the administration of chemotherapy medications, were not chemotherapy certified in accordance with facility policy.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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<td>A 0405</td>
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482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION OF DRUGS

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

This REQUIREMENT is not met as evidenced by:

A 0405

Tag: A 0405
Policy & Procedures:
The Director of Pharmacy, the Pediatrician in Chief, the Chief Nursing Officer and the Director Clinical Quality Improvement reviewed all policies related to chemotherapy ordering, preparing, dispensing and administration and revised and consolidated them into one policy and procedure 30.16 Chemotherapy and Hazardous Medication Management that meets current standards of practice. The Director of Pharmacy and Chief Nursing Officer reviewed the following policies:
30.45 Medication and Intravenous Fluid Orders
30.52 Monitoring the Effects of Medication on Patients
30.56 High Risk Medications Management (High Alert) to ensure that they meet current standards of care and practice and no revisions were required.
Training:
The Director of Pharmacy or qualified designee educated all
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<td>medical, pharmacy and nursing staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy and nursing employee education and annual re-orientation. Any physician who writes orders for chemotherapy will receive education on the policy as part of onboarding to the medical staff. The Chief Nursing Officer and the Director of Professional Development will offer a Chemotherapy Certification course to the nursing department to add additional nursing staff who will be chemotherapy certified. (APHON) The Director of Professional Development and the Director of Pharmacy educated the Nursing staff on the importance of documenting in the electronic medical record any unusual or unexpected events and outcomes related to medication administration including the obligation to document notifications to physician and pharmacy staff.</td>
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The education included review of high-risk medications and staff responsibility to follow existing policy and procedure.

Monitoring:
The Director of Clinical Quality Improvement, the Director of Pharmacy or designees will monitor 100% of chemotherapy patient records concurrently for completion of chemotherapy documentation including evidence of the required double check. The monitoring will continue until there is 100% compliance for 4 consecutive months. The information from monitoring will be reported to the hospital's Quality and Patient Safety Committee on a quarterly basis; and to the Medical Executive Committee and the Governing Board quarterly for review and action as required.

Responsible Person(s):
Director of Professional Development
Chief Nursing Officer
Director of Pharmacy
Pediatrician in chief
Director Clinical Quality Improvement
Disciplinary Action:
Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.
Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.
Based on review of medical records (MR), review of facility documents and policies, and interview with staff (EMP), it was determined that the facility failed to prepare and administer medications in accordance with acceptable standards of practice for one of one medical records reviewed (MR1).

Findings include:

Review of facility policy "Rights and Responsibilities of Patients," dated January 14, 2014, revealed "I) Policy: 1) St. Christopher's Hospital for Children is committed to providing the best possible care to children and youth in a family-centered environment. ... II) Patient Rights: Patients and/or parents or guardians acting on behalf of the patient have a right: ... 3) To provide considerate, respectful care given by competent personnel, including consideration of the psychosocial, spiritual and cultural variables that influence perception of illness. ... 18) To good quality care and high professional standards that are continually maintained and reviewed. ...25) To expect good management techniques to be
#### Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

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<tr>
<th>ID Prefix Tag</th>
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<th>State License Number</th>
<th>Street Address, City, State, Zip Code</th>
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<tr>
<td>A 0405</td>
<td>Continued from page 62</td>
<td>393307</td>
<td>195601</td>
<td>160 EAST ERIE AVE PHILADELPHIA, PA 19134</td>
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- Implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient and family. The patient and the family have the right to expect reasonable safety insofar as hospital practices ... ."

- Review of facility policy "High Risk Medications Management (High Alert)," dated March 2014, revealed "I. Policy SCHC will develop and maintain a list of High Risk Medications. Medications and medication classes on this list will be subject to greater control due to the high potential for errors or consequences of errors. II. Purpose To outline processes for defining, communicating, and enforcing medication management safety measures to promote safe use of high alert high risk medications and reduce medication errors and their consequences. III. Procedure A. Definitions 1. High risk medications: Medications that bear heightened risk of causing significant patient harm when used in error (Institute for Safe Medication Practice ISMP). ... B. Processes will be in effect at every stage of medication management that relates to high risk...
Continued from page 63

medication use. ... 3. Prescribing/Transcribing ... c. Dose range checking is utilized in both PowerChart CPOE and PharmNet. d. When high risk medications are ordered by the provider using an alternative to CPOE, e.g., chemotherapy protocols ..., the relevant orders will be transcribed by the pharmacist into PharmNet and thus into the eMar and PowerChart. e. Down time handling of orders will include double check by the pharmacist of all high risk medication orders and adherence to downtime policies for nursing and providers. 4. Preparation/Dispensing a. Independent double check by the person who prepares the high risk medication and a second person (one of who must be a licensed pharmacist) are mandatory. ... 5. Administration ... b. Independent confirmation of the order and visual confirmation of the medication label by two licensed personnel must occur prior to administration of the medication. ... 6. Monitoring a. Medication events are reported according to the event reporting policy. .... "

Review of MR1 "History and Physical," dated
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October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 "Physicians' Orders," dated October 1, 2015, timed 1030, revealed "... Etoposide (33mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hour at 50 cc/hr. Repeat for 5 days. ... Ifosfamide (60 mg/kg) or 500 mg with MESNA (12mg/kg) 100 mg IV combined & diluted in D5 1/2 NS(200ml/m2) or 80 cc to run over 1 hour at 80 cc/hour. Repeat for 5 days." The physicians' order, written by EMP17 and countersigned by EMP13, did not clarify the location and type of intravenous access device that was to be utilized for administration of chemotherapy medications to the patient.

Review of MR1 "Nursing/Clinical Info," dated...
October 3, 2015, performed at 06:59, by EMP18 revealed "... 01:00: Etoposide given over 2 hrs via left chest port. ... Pt. tolerate well and no adverse reactions noted. ..."

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed ",...01:00: Etoposide given over 2 hours via right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ..."

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 13:44, revealed "Mesna 100 mg 1 mL; d5i25 25 mL IV Chemo, Saphenous [vein in the leg] Left ... Perform: EMP28; Witness:
EMP29 10/6/2015 13:44; Verify EMP28 ... ."
Review of MR1 revealed no documented evidence that a physician's order was obtained to administer Mesna through a vein in the patient's leg. Further review of MR1 revealed a discrepancy as to the location of the actual port that was being utilized to administer chemotherapy medication.

Review of M1 "Physician Progress Notes," dated October 6, 2015, timed: 19:14, revealed " ... This morning 1 [EMP14] was notified of a severe medication error involving the VP-16 (Etoposide) that [patient] had received for the past 5 days. It was found to be a typographical error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... This is 10x the daily dose we intended for [patient]. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, revealed "... Hospital Course:
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<td>A 0405</td>
<td>Continued from page 67 Onc [oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... . The Etoposide precipitated on 10/1, 10/4, and 10/6 due to highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ... On 10/5/15, the last day of [patient's] chemotherapy treatment, the patient was to be discharged but it was discovered that [patient] received an incorrect dose of Etoposide due to an error for the 5 days of chemotherapy. ...&quot;</td>
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2015, EMP11, reviewed the dosing and concentration of Etoposide after being notified by EMP18 that the medication had precipitated (medication separated from the diluent causing it to be deposited in a solid from a solution) during administration; EMP11 identified that the concentration/dose was too high.

Interview on January 11, 2016, at 10:20 AM, with EMP1 indicated that a root cause analysis (RCA) was performed. EMP1 revealed that they didn't know why it took the facility five days to realize that there was an error with the dosage of Etoposide that was being provided to the patient in MR1. EMP1 indicated that the event was due to a "typographical" error made by EMP13. EMP1 indicated that four oncologists, EMP13, EMP14, EMP15 and EMP16, created the custom "Roadmap" to treat the patient's illness. EMP1 indicated that the dose was to be 3.3 [mg/kg] not 33 [mg/kg] but EMP13 wrote down '33' instead of '3.3' and then EMP17 transcribed the order based on what was written on the "Roadmap."
Continued from page 69

Interview on January 11, 2016, at 10:59 AM, with EMP1 confirmed that there was no documented evidence that nursing notified the physician and/or pharmacy of the medication precipitating event on October 2, 2015. EMP1 indicated that "most of the medication was administered by the time it was realized." EMP1 revealed that EMP18 completed an internal report regarding the event and that, according to EMP1, under "what actions were taken" EMP18 documented "no treatment necessary." At 11:09 AM EMP1 revealed that nursing is aware of the causes related to a medication precipitating and indicated that if the patient received "most" of the medication then pharmacy would not be contacted. EMP1 revealed that the facility does not have a policy related to this process.

Review of MR1 revealed no documented evidence regarding the exact amount of medication that the patient received during the first precipitating event that occurred on October 2, 2015 or the second precipitating event that occurred on October 4,
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<td>A 0405</td>
<td>Continued from page 70 2015. Furthermore, there was no documented evidence that the physician and/or pharmacy was notified of the medication precipitating event that occurred on October 4, 2015, prior to October 6, 2015. The facility failed to prepare and administer medications in accordance with acceptable standards of practice.</td>
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### Statement of Deficiencies and Plan of Correction (POC)

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<tr>
<th>Name of Provider or Supplier:</th>
<th>ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN</th>
</tr>
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<tbody>
<tr>
<td>State License Number:</td>
<td>195601</td>
</tr>
<tr>
<td>Street Address, City, State, Zip Code:</td>
<td>160 EAST ERIE AVE PHILADELPHIA, PA 19134</td>
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<th>ID</th>
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<tr>
<td>A 0449</td>
<td>482.24(c) CONTENT OF RECORD</td>
<td>The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.</td>
<td>Status: APPROVED Date: 04/27/2016</td>
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This REQUIREMENT is not met as evidenced by:

- **Tag:** A 449
- **Policy & Procedures:**
  - The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy.
  - Other Corrective Actions:
    - The Director of Health Information and staff will assist the Oncology Department with the development of a standard template for all custom roadmaps. This roadmap template will include labeled space for the physician's signature, date and time as well as for the second verifying physician's signature and the date and time of verification of the roadmap. Literature used to develop custom roadmaps will be attached to the roadmap and scanned into the medical record. In addition, the literature will be supplied to the pharmacist preparing the chemotherapy.
    - **Training:**
      - The Physician-in-Chief sent an email to all physicians on staff on the
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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<td>appropriate and accurate documentation required in the medical record including the requirements for authentication, dating and timing of all entries. The Chiefs of the Medical Staff departments will review the email with their departments at their next department meetings. Monitoring: The Oncology Department will concurrently monitor 100% of the double check verification process including authentication, dating and timing of roadmaps by both the author and the verifier. The results will be reported quarterly to the Quality and Patient Safety Committee. The Director of Health Information Management and staff will monitor medical records for completion of authentication, dating and timing. This information will be aggregated and reported to the Medical Staff Executive Committee at their routine meetings for review and action as required. Responsible Person(s):</td>
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Oncology Section Chief
Physician-in-Chief
Director Clinical Quality Improvement
Director of Health Information Management
Disciplinary Action:
Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.
Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP) it was determined that the facility failed to maintain a complete medical record for one of one medical records reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All entries in a patient's medical record shall be consistent and noncontradictory; information
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recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ... 3) All atypical treatments shall be recorded with explanation as to why the treatments were rendered. a) All usual occurrences/incidents such as falls, medication errors, equipment malfunctions, and emergency situations shall be documented in the record. b) In all incidents, the recorder should objectively document only what was actually witnessed or observed. ... 5) The record must reflect ... physical condition, ... time physicians were notified, and the details of treatment ordered or rendered. ... 8) Physician, specialist, and consultant vitals to the patient and the professional services rendered shall be charted in the progress notes and on a consult form. 9) Documentation shall include: (i) Patient's ... responses to treatment ... . 14) Charting must be objective and leave no room for conjecture, doubt, or misunderstanding of what is being recorded. ... ."
Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication] 1800 mg m2/dose (60 mg/kg/dose if age < 1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m2/dose (12 mg/kg if age < 1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy...
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

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medication] 100 mg/m2/day (33mg/kg if age <1 yr) days 1-5. ... " The " Roadmap " revealed the following handwritten calculation for Etoposide " ... 280 mg ... " Further review of the "Roadmap" revealed that the document was not dated, nor was it authenticated by the individual who transcribed the "Roadmap" and performed the calculations contained on the "Roadmap."

Review of MR1 "Physicians' Orders," dated October 1, 2015, revealed " ... Etoposide (33 mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hours at 50 cc/hr. Repeat 5 days. ... "

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.
Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21]; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 5, 2015.

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that nursing "documents by exception" meaning that "they document unusual occurrences."

Interview on February 4, 2016, at 9:09 AM, with EMP10 revealed that literature was used to develop the patient's treatment protocol, a customized "Roadmap." EMP10 revealed that the literature was not include in the patient's medical record nor was it sent to pharmacy, with the "Roadmap" and physician orders.
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)</th>
<th>COMPLETE DATE</th>
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<td>A 0449</td>
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### Statement of Deficiencies and Plan of Correction (POC)

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<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
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<td>A 0465</td>
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#### 482.24(c)(4)(iv) CONTENT OF RECORD: COMPLICATIONS

[All records must document the following, as appropriate:] Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

This REQUIREMENT is not met as evidenced by:

- Tag: A465
- Policy & Procedures: The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy.
- Training: The Chief Nursing Officer and the Risk Manager educated the Nursing staff on the Charting Guidelines policy and procedure and the importance of accurate, complete and through documentation. This included the importance of documenting all unusual or unexpected events and outcomes related to medication administration in the electronic medical record and including the obligations to document notifications to physician and pharmacy staff in the electronic medical record.
- Monitoring: The Risk Manager monitors any reported events that are coded in the incident reporting system as a level D or above and checks to see if the
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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

**Multiple Construction:**
- **A. BLDG:** ____________
- **B. WING:** ____________

**Completed Date:** 03/09/2016

**Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced To The Appropriate Column Of Deficiencies (Each Deficiency Must Be Preceded By Full Regulatory Or LSC Identifying Information)**

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<th>(X5) Complete Date</th>
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<td>A 0465</td>
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<td>Continued from page 81</td>
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Documentation of the event is included in the patient's electronic medical record. This information will be included as trended data and reported to the Quality and Patient Safety Committee quarterly for review and for action as required. The Oncology patient records will be monitored and reviewed to ensure that the medical record contains nursing/clinical information during the chemotherapy infusions and that nursing records all unusual occurrences/incidents in the medical record. This information will be included as trended data and reported to the Quality and Patient Safety Committee quarterly for review and for action as required.

Responsible Person(s):
- Director of Professional Development
- Director of Risk Management
- Chief Nursing Officer
- Director of Continuous Quality Improvement

Disciplinary Action:
- Non-compliance with corrective action by hospital staff will result in
### Statement of Deficiencies and Plan of Correction (POC)

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<td>A 0465</td>
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<td>A 0465</td>
<td>Immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.</td>
</tr>
</tbody>
</table>

**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:**

- A 0465

**Date Survey Completed:** 03/09/2016

**State of Identification Number:** 393307

**Date Survey Completed:** 03/09/2016

**State License Number:** 195601

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

**Printed:** 11/30/2016

**Form Approved:** 2567-L
Based on review of medical records (MR), review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to adequately document complications for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All entries in a patient's medical record shall be consistent and noncontradictory; information
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<td>A 0465</td>
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<td>Continued from page 84 recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ... 3) All atypical treatments shall be recorded with explanation as to why the treatments were rendered. a) All usual occurrences/incidents such as falls, medication errors, equipment malfunctions, and emergency situations shall be documented in the record. b) In all incidents, the recorder should objectively document only what was actually witnessed or observed. ... 5) The record must reflect ... physical condition, ... time physicians were notified, and the details of treatment ordered or rendered. ... 8) Physician, specialist, and consultant vitals to the patient and the professional services rendered shall be charted in the progress notes and on a consult form. 9) Documentation shall include: (i) Patient's ... responses to treatment .... 14) Charting must be objective and leave no room for conjecture, doubt, or misunderstanding of what is being recorded. ... &quot;</td>
<td>A 0465</td>
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</table>
Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 "Medication Administration," dated October 2, 2015, timed: 00:52, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP19] 10/02/2015 00:52; Verify: [EMP18] ... ."

Review of MR1 "Nursing/Clinical Info," dated October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results
Continued from page 86

wnl to begin chemo. 2315: Loading dose of zofran given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosfamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn given (abx compatible with Mesna per pharmacy). Mesna boluses to be given hrs 3, 9, 12. [Patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor."

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP20] 10/03/2015 00:53; Verify: [EMP 18] ...

Review of MR1 "Nursing/Clinical Info," dated
Continued from page 87

October 3, 2015, performed at 06:59, by EMP18 revealed "... 01:00: Etoposide given over 2 hrs via left chest port. ... Pt. tolerate well and no adverse reactions noted. ..."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on
<table>
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<th>ID PREFIX</th>
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<th>(X3) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307</th>
<th>(X4) DATE SURVEY COMPLETED: 03/09/2016</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>(X5) COMPLETE DATE</th>
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<td>A 0465</td>
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October 5, 2015.

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP23] 10/04/2015 00:55; Verify: [EMP18] ... ."

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed "...01:00: Etoposide given over 2 hours via right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ... ."

Review of MR1 "Physician Progress Notes," dated
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<td>A</td>
<td>0465</td>
<td>October 6, 2015, authenticated by EMP14, at 20:49, revealed &quot;This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ...&quot;</td>
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|     |     | Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed " ... Hospital Course: ONC
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<td>A 0465</td>
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<td>[Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ...”</td>
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Review of MR1 revealed a discrepancy in between the date when the patient's medication first precipitated. Review of MR1 revealed that the administration of chemotherapy was started on the patient on October 2, 2015.

Further review of MR1 revealed no documentation pertaining to the two medication precipitating events that occurred prior to October 6, 2015.

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 revealed that a medication can precipitate if the concentration is too high or if there is not enough diluent. EMP1 confirmed that nursing
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<td>A 0465</td>
<td>Continued from page 91 is aware of what can cause a medication to precipitate. EMP1 confirmed that nursing did not document this event in the patient's medical record and revealed that nursing &quot;documents by exception&quot; meaning that &quot;they document unusual occurrences.&quot; EMP1 confirmed that nursing should have documented this event in the patient's medical record. At 10:59 AM EMP1 indicated that &quot;most of the medication was administered by the time it was realized.&quot; Review of MR1 revealed no documented evidence regarding the exact amount of medication that the patient received during the first precipitating event on October 2, 2015 and during the second precipitating event that occurred on October 4, 2015.</td>
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<td>Completion Date: 05/06/2016 Status: APPROVED Date: 04/28/2016</td>
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482.24(c)(4)(vi) CONTENT OF RECORD: ORDERS, NOTES, REPORTS

[All records must document the following, as appropriate:] All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

This REQUIREMENT is not met as evidenced by:

Tag: A 467 Policy & Procedures:
The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy.

The Director of Pharmacy and the Chief Nursing Officer reviewed the policy and procedure on Medication Monitoring to ensure it meets current standards of practice. No revisions to the policy were required at this time.

The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:

The Oncology medical staff will:
- use a double checks process for the road map for each individual patient;
- conduct a physician to physician or a physician to CRNP accuracy check prior to orders being written and sent to the pharmacy.

The Pharmacy staff will:
### 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  
**Completed Date:** 03/09/2016

### Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

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<td>A 0467</td>
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The Nursing Staff will:
- require two chemotherapy certified (APHON) nurses to complete the double check process and document it so that a certified chemotherapy nurse may administer the chemotherapy.

The revised policy was reviewed and approved at the Pharmacy and Therapeutics Committee on April 11, 2016.

Training:
The Chief Nursing Officer and the Risk Manager educated the Nursing
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staff on the Charting Guidelines policy and procedure and the importance of accurate, complete and through documentation. This included the importance of documenting all unusual or unexpected events and outcomes related to medication administration in the electronic medical record and including the obligations to document notifications to physician and pharmacy staff in the electronic medical record.

The Director of Pharmacy or qualified designee educated all medical, pharmacy and nursing staff on the revised policy related to Chemotherapy and Hazardous Medication Management. Monitoring:

The Director of Pharmacy or designee reviews 100% of the chemotherapy orders using the Pharmacy Antineoplastic Drug Profile as a source document. This information is reported to the Quality and Patient Safety Committee quarterly for review and action as required. The Risk Manager
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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monitors any reported events that are coded in the incident reporting system as a level D or above and checks to see if the documentation of the event is included in the patient's electronic medical record. Oncology patient's medical records will be monitored to ensure that the medical record contains nursing/clinical information related to chemotherapy infusions and the medical record contains a description of any unusual occurrences/incidents, and that the road may is included as part of the medical record. This information will be included as trended data and reported to the Quality and Patient Safety Committee quarterly for review for action as required.

Responsible Person(s):
- Section Chief of Oncology
- Director of Nursing
- Director of Pharmacy
- Director Clinical Quality Improvement
- Director of Risk Management
- Disciplinary Action: Non-compliance with corrective
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<td>action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate</td>
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Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that necessary information was included in a patient's medical record in order to adequately monitor a patient's condition and provide appropriate care for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) **POLICY:** To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) **PROCEDURE:** ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All
entries in a patient's medical record shall be consistent and noncontradictory; information recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ... 3) All atypical treatments shall be recorded with explanation as to why the treatments were rendered. a) All unusual occurrences/incidents such as falls, medication errors, equipment malfunctions, and emergency situations shall be documented in the record. b) In all incidents, the recorder should objectively document only what was actually witnessed or observed. ... 5) The record must reflect ... physical condition, ... time physicians were notified, and the details of treatment ordered or rendered. ... 8) Physician, specialist, and consultant vitals to the patient and the professional services rendered shall be charted in the progress notes and on a consult form. 9) Documentation shall include: (i) Patient's ... responses to treatment ... . 14) Charting must be objective and leave no room for
A 0467 Continued from page 99

conjecture, doubt, or misunderstanding of what is being recorded. ...."

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication]1800 mg m2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication]360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9.
Give 100% mesna. Etospose [chemotherapy medication] 100 mg/m²/day (33mg/kg if age <1 yr) days 1-5. The "Roadmap" revealed the following handwritten calculation for Etoposide "... 280 mg ..."

Review of MR1 "Nursing/Clinical Info," dated October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results wnl to begin chemo. 2315: Loading dose of zofran given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosphamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn...
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given (abx compatible with Mesna per pharmacy). Mesna boluses to be given hrs 3, 9, 12. [Patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on
October 5, 2015.

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."
Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed "... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ..."

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 confirmed that nursing did not document this event in the patient's medical record.

Interview on February 4, 2016, at 9:00AM, with EMP9 revealed that EMP13 typed the customized "Roadmap."

Interview on February 4, 2016, at 9:09 AM, with EMP10 revealed that literature was used to develop...
A 0467  Continued from page 104

the patient's treatment protocol, the customized "Roadmap." EMP10 revealed that the literature was not included in the patient's chart nor was it sent to pharmacy to allow for pharmacy to review with the "Roadmap" prior to filling the orders. EMP10 revealed that the literature used to develop customized "Roadmaps" would "sometimes" be sent to pharmacy, "but not always." EMP10 revealed that the facility did not have an established policy for this process.

The facility failed to ensure that necessary information was included in a patient's medical record in order to adequately monitor a patient's condition and provide appropriate care.

A 0490  Continued from page 104
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

DATE SURVEY COMPLETED: 03/09/2016

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)
(X4) ID PREFIX TAG
A 0490 Continued from page 105

ID PREFIX TAG
A 0490

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DATE)

Completion Date: 05/06/2016
Status: APPROVED
Date: 04/28/2016

482.25 PHARMACEUTICAL SERVICES

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

This REQUIREMENT is not met as evidenced by:

Tag: A490
Policy & Procedures:
The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:
The Pharmacy staff will:
- have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map;
- use the revised Antineoplastic Drug Profile check list to document the verification process for orders;
- document the independent double check completed by pharmacy staff and;
- complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy;
The Director of Pharmacy reviewed and revised the Pharmacy Antineoplastic Drug Profile Checklist. The checklist will be maintained in the patient's medication profile, and includes a
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<td>A 0490</td>
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<td>record of who prepared the chemotherapy, who completed the double check process, a checklist to ensure that a review of the road map was completed and compared to the written order, and access to the research the road map is based on. Training: The Director of Pharmacy or qualified designee educated all pharmacy staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy employee education and annual re-orientation. The Director of Pharmacy assigned all pharmacists who prepare chemotherapy to a chemotherapy training class. Pharmacists completed the class and passed a post training test. The chemotherapy class and post-test will become part of pharmacy annual re-orientation. The Director of Pharmacy educated all Pharmacy and Oncology Medical staff on the revised Pharmacy Antineoplastic Drug Profile process to ensure that research materials are available</td>
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|--------------|-------------------------------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------
| A 0490       | Continued from page 107                                                                         | A 0490       | available for Pharmacy review. Monitoring: The Director of Pharmacy and the Director of Nursing will monitor patient records to ensure that all pharmacy staff preparing chemotherapy will have access to the literature related to the research resources; the custom road map; use the revised antineoplastic drug profile check list that documents the verification and double check process. A report will be submitted quarterly to the Quality and Patient Safety Committee for review and action as required. Responsible Person(s): Director of Pharmacy Director of Clinical Quality Improvement Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. |
Based on review of medical records (MR), review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to provide pharmaceutical services that met the needs of a patient by promoting a safe medication use process as evidence by: failing to ensure that all pharmacists engaging in the preparation and dispensing of chemotherapy medications received specialized training in order to provide quality services, maintain competency and meet the needs of the patient population being served (A0493); and failing to ensure that medication orders were adequately reviewed for appropriateness and prepared, in accordance with facility policy, prior to dispensing (A500).

Cross Reference:
482.13 Patient Rights
482.13(c)(2) Patient Rights: Care in Safe Setting
482.25(a)(2) Pharmacy Personnel
482.25(b) Delivery of Drugs
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

**ID PREFIX TAG**  | **SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)** | **ID PREFIX TAG** | **PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE** | **COMPLETE DATE**
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**482.25(a)(2) PHARMACY PERSONNEL**

The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

This REQUIREMENT is not met as evidenced by:

Tag: 493

Policy & Procedures:
The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:
The Pharmacy staff will:
- have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map;
- use the revised Antineoplastic Drug Profile check list to document the verification process for orders;
- document the independent double check completed by pharmacy staff and;
- complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy.

Training:
The Director of Pharmacy assigned all pharmacists who prepare chemotherapy to a chemotherapy training class. Pharmacists completed the class and passed a
## 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

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

**DATE SURVEY COMPLETED:**

03/09/2016

**PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)**

- **ID PREFIX**
  - A 0493

- **STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)**

- **A 0493**

  post training test. The chemotherapy class and post-test will become part of pharmacy annual re-orientation.

  Monitoring:

  The Director of Pharmacy will ensure that all staff preparing chemotherapy have received and successfully passed the chemotherapy training program. The records will be maintained in the staff personnel files.

  Responsible Person(s):

  Director of Pharmacy

  Chief Nursing Officer

  The Director of Pharmacy will monitor that 100% of the custom road maps have the available research resources for pharmacy staff’s reference. The audit results will be presented to the hospitals’ Quality and Patient Safety Committee on a quarterly reporting schedule for review and action as required.
Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that all pharmacists engaging in the preparation and dispensing of chemotherapy medications received specific training in order to provide quality services, maintain competency and meet the needs of the patient population being served for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Rights and Responsibilities of Patients," dated January 14, 2014, revealed "I) Policy: 1) St. Christopher's Hospital for Children is committed to providing the best possible care to children and youth in a family-centered environment. ... II) Patient Rights: Patients and/or parents or guardians acting on behalf of the patient have a right: ... 3) To provide considerate, respectful care given by competent personnel, including consideration of
### 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

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

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The psychosocial, spiritual and cultural variables that influence perception of illness. ... 18) To good quality care and high professional standards that are continually maintained and reviewed. ...25) To expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient and family. The patient and the family have the right to expect reasonable safety insofar as hospital practices ...

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ...

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

**(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:**

393307

**(X2) DATE SURVEY COMPLETED:**

03/09/2016

**STATE LICENSE NUMBER:**

195601

**STREET ADDRESS, CITY, STATE, ZIP CODE:**

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PHILADELPHIA, PA  19134

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Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosfamide [chemotherapy medication] 1800 mg m2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr Cl, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m2/day (33mg/kg if age <1 yr) days 1-5. ..." The "Roadmap" revealed the following handwritten calculation for Etoposide "... 280 mg ..."

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose.
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<td>Continued from page 115 based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ...&quot;</td>
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requires it. EMP1 revealed that these pharmacists "have been here for years but that they received training during orientation on pediatric dosing and mixing chemotherapy medications." EMP10 revealed that as a result of the medication error, involving Etoposide, the pharmacists working in oncology will rotate as to who prepares chemotherapy medications in order to maintain competency.

On January 26, 2016, at 9:03 AM, a request was submitted to EMP9 for a list of the actual pharmacists who prepared and dispensed Etoposide on October 2, 3, 4, 5, and October 6, 2015. EMP9 was also asked for a copy of their last training/education that each pharmacist received regarding chemotherapy pharmacy.

Review of correspondence submitted to the Department, on January 28, 2016, at 4:22 PM, from EMP9 revealed that the facility did not have record as to which pharmacists actually prepared and dispensed Etoposide each day. EMP9 indicated
that the pharmacist signs the label after it is printed, but then the label is discarded once the medication is finished. EMP9 revealed that there are no specialized educational requirements or oncology specific requirements that are required of the pharmacists in order to work in oncology. EMP9 indicated that "... pharmacists orient with [EMP4] in the oncology clinic checking and verifying orders and learning the processes involved until they feel that they can handle clinic and chemotherapy admissions. This is usually a 3 to 6 month period depending on it they have any prior experience.

The facility failed to ensure that all pharmacists engaging in the preparation and dispensing of chemotherapy medications received specific training in order to provide quality services, maintain competency, and meet the needs of the patient population being served.
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In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

This REQUIREMENT is not met as evidenced by:

482.25(b) DELIVERY OF DRUGS

Policy & Procedures:
The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:
The Pharmacy staff will:
- have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map;
- use the revised Antineoplastic Drug Profile check list to document the verification process for orders;
- document the independent double check completed by pharmacy staff and complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy that has been prepared;
The Director of Pharmacy reviewed and revised the Pharmacy Antineoplastic Drug Profile Checklist. The checklist will be...
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Maintained in the patient's medication profile, and includes a record of who prepared the chemotherapy, who completed the double check process, a checklist to ensure that a review of the road map was completed and compared to the written order, and access to the research the road map is based on.

Training:
The Director of Pharmacy or qualified designee educated all pharmacy staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy employee education and annual re-orientation. The Director of Pharmacy educated all Pharmacy and Oncology Medical staff on the revised Pharmacy Antineoplastic Drug Profile process to ensure that research materials are available for Pharmacy review.

Monitoring:
The Director of Pharmacy will monitor that 100% of the custom...
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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

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**SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)**

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**PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE**

| A 0500 | Continued from page 121 |

Road maps have the available research resources for pharmacy staff’s reference. The audit results will be presented to the hospitals’ Quality and Patient Safety Committee on a quarterly reporting schedule for review and action as required.

**Responsible Person(s):**
- Director of Pharmacy
- Chief Nursing Officer
- Section Chief of Oncology

**Disciplinary Action:**
Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital’s Human Resources policies and procedures.

Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.
Based on review of medical records (MR), review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that medication orders were adequately reviewed for appropriateness and prepared, in accordance with facility policy, prior to dispensing for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Chemotherapy and Hazardous Medication Management," dated March 2014, revealed "**I. Policy** A. Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ... these medications. **II. Purpose** Certain medications carry unique hazards. This policy promotes knowledge and understanding of these effects and how to mitigate them except as applied to patient
**Therapy. Policy will dictate the handling of these medications in a way that promotes better patient care and safety.** IV. Procedure A. Chemotherapy.

2. Order processing, preparation and handling a. The pharmacist receiving the order (pharmacist #1) i. Will review the order for patient appropriateness and clarify the order with the ordering heme/one attending when necessary. ii. Will check the pertinent laboratory data. iii. Will enter the order into the computer to generate a patient charge and a label for the drug which includes: ... k) Initials of preparer and the checker ... iv. Must retrieve the patient chemotherapy profile in the Oncology Clinic (if it exists) or create a new patient folder and profile. ... b. Pharmacist #1 will complete the Pharmacy Drug Profile sheets for each drug in the order. Pharmacist #2 will verify the work. ... d. Each chemotherapeutic agent must be admixed individually by a pharmacy technician and all work checked by a pharmacist. i. Chemotherapeutic agents will be prepared by personnel specially trained in chemotherapy handling. ... e. Both pharmacists will retrieve and**
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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

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

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<td>review the label, the order, and the patient profile; then review admixing instructions with the pharmacy technician utilizing package inserts and other references needed. f. Prior to having a certified chemo technician complete the preparation of products, the pharmacist will call a second pharmacist (pharmacist #2) to check the following: i. The original orders against the printed label and all calculations ii. The original orders against the protocol and roadmap (chemotherapy profile) ... g. ... vi. The preparer will affix the prepared label and precautionary labels to the final product and indicate completeness by initialing the chemotherapy profile. h. The pharmacist witnesses the technician completing the preparation, initials the label, and initials the chemotherapy profile. ... j. The patient chemotherapy order form will be placed in the chemotherapy file for future reference. ... &quot;</td>
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Review of facility policy "High Risk Medications Management (High Alert)," dated March 2014, revealed "I. Policy SCHC will develop and maintain a list of High Risk Medications. Medications and
medication classes on this list will be subject to greater control due to the high potential for errors or consequences of errors. II. Purpose To outline processes for defining, communicating, and enforcing medication management safety measures to promote safe use of high alert high risk medications and reduce medication errors and their consequences. III. Procedure A. Definitions 1. High risk medications: Medications that bear heightened risk of causing significant patient harm when used in error (Institute for Safe Medication Practice ISMP). ... B. Processes will be in effect at every stage of medication management that relates to high risk medication use. ... 3. Prescribing/Transcribing ... c. Dose range checking is utilized in both PowerChart CPOE and PharmNet. d. When high risk medications are ordered by the provider using an alternative to CPOE, e.g., chemotherapy protocols ... , the relevant orders will be transcribed by the pharmacist into PharmNet and thus into the eMar and PowerChart. e. Down time handling of orders will include double check by the pharmacist of all high risk medication orders and adherence to
### 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**

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<td>Continued from page 126 by the person who prepares the high risk medication and a second person (one of who must be a licensed pharmacist) are mandatory. ...&quot;.</td>
<td>A 0500</td>
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Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "...1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of cancer. Review of the "Roadmap" revealed "...ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication] 1800 mg m2/dose (60
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<td>A 0500</td>
<td>Continued from page 127 mg/kg/dose if age &lt;1 yr) days 1-5; Mesna [chemotherapy medication]360 mg/m2/dose (12 mg/kg if age &lt;1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m2/day (33mg/kg if age &lt;1 yr) days 1-5. ... &quot; The &quot; Roadmap &quot; revealed the following handwritten calculation for Etoposide &quot; ... 280 mg ... &quot;</td>
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<td>Review of MR1 &quot;Physicians' Orders,&quot; dated October 1, 2015, revealed &quot;... Etoposide (33 mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hours at 50 cc/hr. Repeat 5 days. &quot;</td>
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<td>Review of MR1 &quot;Orders,&quot; dated October 1, 2015, revealed &quot;... Etoposide ... Order Details: 280 mg= 14 mL, Injection, IV Chemo, ... Pharmacist Verify: Electronically Signed, EMP12 on 10/1/2015 16:10 ...&quot;.</td>
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<td>Review of MR1 &quot;Nursing/Clinical Info,&quot; dated October 6, 2015, performed at 04:55, by EMP18 revealed &quot;...01:00: Etoposide given over 2 hours via</td>
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right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ..."

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is
Continued from page 129

10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed " ... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ... RESIDENT A/P Assessment: ... After discovering the incorrect Etoposide dose, [the patient] was closely monitored. ... Patient is being closely monitored for possible liver, renal, bone marrow, neurologic, and respiratory damage secondary to potential Etoposide toxicity. Plan:
**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

**IDENTIFICATION NUMBER:** 393307

**DATE SURVEY COMPLETED:** 03/09/2016

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<td>A 0500</td>
<td>Continued from page 130 Oncology: Completed chemotherapy 10/6 ... patient awaiting transfer to [another health care facility] on 10/6/2015. ...&quot; Interview on January 11, 2016, at 10:00 AM, with EMP1 and EMP10 revealed that EMP12 and EMP31 prepared and dispensed the Etoposide on October 2, 2015 but they were unsure as to who prepared and dispensed the Etoposide on October 3, 4, 5, and October 6, 2015. EMP1 indicated that pharmacy only verifies the order once for a &quot;multiple fill order,&quot; they do not complete the full verification process on each day the medication is being prepared and dispensed. EMP1 indicated that the pharmacists receive the order and check it with the &quot;Roadmap&quot; and then verify the dose. Review of correspondence submitted to the Department, on January 28, 2016, at 4:22 PM, from EMP9 revealed that the facility did not have record as to which pharmacists actually prepared and dispensed Etoposide each day. EMP9 indicated that the pharmacist signs the label after it is printed,</td>
<td>A 0500</td>
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but then the label is discarded once the medication is finished.

There was no documented evidence that pharmacy reviewed the physician's order for accuracy and appropriateness, nor completed the verification and check process, in accordance with facility policy.
This report is the result of an unannounced State investigation survey conducted onsite on October 29, 2015, at St. Christopher's Hospital for Children and completed off-site on March 9, 2016. 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.
continued from page 1

103.4 (3) FUNCTIONS

(3) Take all reasonable steps to conform to all applicable Federal, State, and local laws and regulations.

This REGULATION is not met as evidenced by:

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<td>P 0317</td>
<td>All exhibits including revisions to Medical staff Bylaws, reviewed/revised or promulgated policies and procedures, documentation of staff and medical staff training/education are retained at the facility for agency review and verification upon request.</td>
<td>P 0317</td>
<td>Policy &amp; Procedures: The Serious/Sentinel Event Reporting, the Medication Event Report and Interdisciplinary Review and Evaluation and the Event Reporting policy were reviewed by the Director of Risk Management and the Director of Continuous Clinical Quality. No revisions to the policy were necessary.</td>
<td>Completion Date: 05/06/2016</td>
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Training: All Quality and Patient Safety staff received training on February 23 2016 in regard to manual entry of safety event reports into PSRS.

Monitoring: The Director of Risk Management will monitor that all
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**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):**

Serious safety events and infrastructure failures are reported to PSRS (and to the Department of Health through PSRS) within 24 hours and all incidents are entered into the PSRS system in a timely manner. This monitoring will take place on a monthly basis and will be reported to the CQOEPS committee on a quarterly basis.

Other Corrective Actions: Quality and Safety leadership will ensure that all incidents are entered into PSRS in a timely manner and that all serious safety events are reported within 24 hours. Until such time that an interface between the Quantros event reporting system and PSRS system has been established a manual process has been established to ensure that all incidents are reported in a timely manner. This process was implemented on February 23, 2016 and will be completed by May 6, 2016. Serious safety events will be entered manually into the PSRS system with 24 hours of occurrence.
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<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)</th>
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<td>393307</td>
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<td>Responsible Person(s): Director of Quality, Director of Risk Management, Patient Safety Officer</td>
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<td>Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures. Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.</td>
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Based on a review of medical records (MR), facility documents and interview with staff (EMP), it was determined the facility failed to conform to all applicable State laws.

St. Christopher's Hospital for Children was not in compliance with the following State law:

Act 13 of 2002, Medical Care Availability and Reduction of Error (MCARE) Act 40 PS. §1303.302 Definitions ... "Incident." An event, occurrence or situation involving the clinical care of a patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. "Serious event." An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident. ... PS. §1303.313 Medical facility reports and notifications. (a) Serious
event reports. --A medical facility shall report the occurrence of a serious event to the department and the authority within 24 hours of the medical facility confirmation of the occurrence of the serious event. The report to the department and the authority shall be in the form and manner prescribed by the authority in consultation with the department and shall not include the name of any patient or any other identifiable individual information. (b) Incident reports. --A medical facility shall report the occurrence of an incident to the authority in a form and manner prescribed by the authority and shall not include the name of any patient or any other identifiable individual information. (c) Infrastructure failure reports. -- A medical facility shall report the occurrence of an infrastructure failure to the department within 24 hours of the medical facility's confirmation of the occurrence or discovery of the infrastructure failure. The report to the department shall be in the form and manner prescribed by the department. (d) Effect of report. -- Compliance with this section by medical facility shall satisfy reporting requirements of the act of July 19, 1979 (P.L. 130,
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No. 48), known as the Health Care Facilities Act.

This is not met as evidence by:

Based on review of medical records (MR), review of facility documents, review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to report reportable events through the Patient Safety Reporting System (PSRS).

Findings include:

Review of facility policy "Medication Event Report and Interdisciplinary Review and Evaluation," dated May 13, 2014, revealed "I. **POLICY** A. St. Christopher's Hospital for Children, as a patient care environment, encourages the reporting of adverse drug events and potential adverse drug events. All staff members with a role in the medication use process are required to participate in the detection and reporting of medication reactions, medication errors or near misses and to assist in the
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evaluation of system based causes for these events. Data gathered through medication event reporting are analyzed and trended for the purpose of minimizing or avoiding future medication errors and to improve the quality of patient care and processes related to medication use. ... I. **PURPOSE** This policy serves as written guideline for identifying, reporting, documenting, and interdisciplinary review of medication events. A positive, proactive and educational approach will be utilized to enhance information gathering surrounding the medication process. II. **PROCEDURE** A. **Definitions** 1. **Medication Error:** A medication error (adverse drug event) is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; ... , compounding; dispensing; distribution; administration; education; monitoring; and use. 2. **Near Miss:** An event caused by a process
3. **Adverse drug reaction (ADR):** an event following administration of a medication which is noxious, unintended, and occurs after doses used in human for prophylaxis, diagnosis or therapy.

4. **ADR classification Criteria:**
   a. **Definitive:** the reaction occurred or was first noted after administrating the medication (patient challenged), ceased or diminished (patient improved) when the drug was stopped (patient de-challenged), and recurred when the drug was re-administered (patient re-challenged). A known association of the reaction with the medication supports this classification.
   c. **Possible:** the reaction appears to be due to the medication.

5. **Event Report Form:** Events are reported online using eSRM/Quantros web site. Alternatively events can be called in by telephone using the event hotline.

6. **Pharmacy Interventions:** A pharmacist initiated interaction with the prescriber of a medication or IV fluid to correct an actual or potential adverse event. Interventions are of the...
**St. Christopher's Hospital for Children**

**State License Number:** 195601

**Address:**
160 East Erie Ave
Philadelphia, PA 19134

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**Severity Level**

Two categories are assigned for each medication error. This reporting system is from the National Consulting Council for Medication Error Reporting and Prevention (NCC MERP). **Error, No Harm** Category C An error occurred that reached the patient but did not cause patient harm. **Error, No Harm** Category D An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm. **Error, Harm** Category E An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention. **Error, Harm** Category F An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization. **Error, Harm** Category G An error occurred that may have contributed to or resulted in permanent patient harm. **Error, Harm** Category H An error occurred that required intervention necessary to sustain life. B. Reporting 1. It is the...
**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

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

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

**DATE SURVEY COMPLETED:** 03/09/2016

**MULTIPLE CONSTRUCTION:**

| A. BLDG: | ________________ |
| B. WING: | ________________ |

**Responsibility of any employee who discovers, witnesses, ...**

2. The report will include the following information: f. date and time or reaction or incident ...

i. Suspected drug or drug involved in the event j. Description of the reaction or event k. Description of what action was taken following the reaction or event l. Contributing factors 3. The individual reporting the error will also report any event ranked at or greater than Severity Level C to the physician caring for the patient and additional appropriate staff. This will include the attending physician, nursing supervisor or department manager. 4. The manager or supervisor in conjunction with the attending physician will conduct the initial investigation and note any action taken and recommendations for prevention. ... C. Report Completion D. The conclusions from the investigation will be entered into the electronic reporting system by the department manager. ... F. Data Evaluation and Analysis of ADRs. ADRs must be categorized in three ways. 1. Classification of the reaction. This classifies the ADR according to the likelihood of the suspected reaction being caused by...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)  

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307  

(X2) MULTIPLE CONSTRUCTION:  
A. BLDG: 00  
B. WING:  

(X3) DATE SURVEY COMPLETED: 03/09/2016  

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

(P) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307  

(P) DCID:  

(P) DATE SURVEY COMPLETED: 03/09/2016  

(P) NAME OF PROVIDER OR SUPPLIER: ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  

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

(P) STATE LICENSE NUMBER: 195601  

(P) PRINTED: 11/30/2016 FORM APPROVED  

(P) ID PREFIX TAG  

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(P) COMPLETE DATE  

(P) Continued from page 11  

(P) the medication in question. 2. Severity Index. This classifies the ADR according to the severity of the patient outcome. 3. Preventability. This index classifies to the extent possible the preventability of the ADR. Any positive answer to the following questions implies that the reaction was preventable. ... b. Was the dose ... inappropriate for the patient's age, weight, ... c. Was required therapeutic drug monitoring or other necessary laboratory tests not performed. ... H. Responsibilities 1. It is the responsibility of those charged with participation in the Medication Safety WorkGroup to review events and reports and to provide recommendations and strategies to enhance the safety of the medication use process at St. Christopher's Hospital for Children. ... 2. The report and recommendations are sent to Pharmacy and Therapeutics Committee, the Quality Committee, Medical Executive Committee and the Board of Governance. 3. In it the responsibility of all health care providers to report adverse medication reactions and potential or actual medication errors. Under reporting is forsaking the caregiver's patient care responsibility and hinders
opportunities for improvement. All employees and medical staff are responsible for compliance with this policy."

Review of facility policy "Serious/Sentinel Event Reporting," last reviewed January 22, 2013 revealed "... II) POLICY: To establish a policy for identifying and reporting serious and sentinel events at St. Christopher's Hospital for Children in order to improve patient care and to satisfy licensure and accreditation requirements. ... IV) DEFINITIONS: 1) Adverse Event means an untoward incident, therapeutic misadventure, iatrogenic injury or other unexpected event with the potential for harm but may meet the definition of a sentinel events and is directly associated with the care of services provided within the hospital. ... 3) Care Associated with a Preventable Events refers to the care directly related to provider error or process failure which resulted in a preventable event with significant harm. ... 15) Root Cause Analysis means a process for identifying the base or contributing causal factors that underlie variations in performance associated
with adverse events, sentinel events or near misses. 16) Sentinel Event means an unexpected event involving the death or serious physical or psychological injury or the risk thereof. Serious injury specifically includes the loss of limb or function not related to the natural course of the patient's illness or underlying conditions. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. ..."

Review of facility policy "Event Reporting," dated July 2013, revealed **I) SCOPE:** This policy applies to St. Christopher's Hospital for Children and its Medical Staff. ... **II) PURPOSE:** 1) The purpose of this policy are to: a) Clarify and delineate the responsibilities of Hospital Staff Members, as defined in below, with respect to reportable events involving patients are/or visitors; b) Provide a system for promptly reporting and investigating reportable events and integrating risk reduction strategies into Hospital's performance improvement activities; c) Comply with the requirements of
applicable federal and state law and the standards of applicable accrediting organizations as they relate to reportable event requirements; d) Establish a process to validate documentation and investigation is conducted appropriately to the type and level of security of reportable events; and e) Support a culture of shared accountability for the identification, reporting and management of reportable events that may impact quality of care provided. III) DEFINITIONS: 1) **Reportable Event** means an event that is not consistent with the routine operation of the Hospital or the routine care of a patient or patients. The potential for accident, injury, illness or property damage commonly referred to as a "Near Miss" is sufficient for an event to be considered a Reportable Event. Reportable Events may also include an unintended event or act of omission or commission that departs from or fails to achieve what was intended ... Reportable Events may or may not result in negative consequences to the patient. Reportable Events may include ... an individual error of judgement or action or inaction. ... 4) **Event Report** means a confidential, internal
electronic or paper document used for early reporting of events for identification of patient safety issues and performance improvement initiatives. This form is not part of the medical record. ... 7) **Infrastructure** (under Pennsylvania Act 13) is structure related to the physical plant and service delivery systems necessary for the provision of health care services in a medical facility. **8) Infrastructure Failure** (under Pennsylvania Act 13) is an undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service, which could seriously compromise patient safety. To be considered an Infrastructure failure, a report must meet all of the criteria: An undesirable or unanticipated event, occurrence or situation involves the infrastructure of a medical facility and could seriously compromise patient safety OR an undesirable or unanticipated event, occurrence or situation involves the discontinuation or significant disruption of a service and could seriously compromise patient safety. **9) Incident** (under Pennsylvania Act 13) is an event, occurrence
or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient. The term does not include a serious event. To be considered an incident, the event must meet the following criteria: Involve the clinical care of a patient in a medical facility and could have injured the patient but did not cause an unanticipated injury requiring additional healthcare services to the patient. **10) Near Miss** is an occurrence or situation directly associated with care or services provided within the hospital that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Near misses do not impact the patient's plan of care but a recurrence would carry a significant chance of impacting another patient's plan of care. ... **13) Serious Event** (Under Pennsylvania Act 13) is an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of
additional health care services to the patient. ... V) **PROCEDURE:** 1) Time Frame for Completing an Event Report  a) After providing for the needs of the individuals involved, or when an event is discovered, the healthcare worker shall complete and submit an event report as soon as possible. ... Report submission for reports of this nature is to occur upon discovery but no later than twenty-four (24) hours after discovery.  2) Information to Provide in the Event Report  a) When completing an Event Report, Hospital Staff Members should have key information available for completing the report, such as:  * If the event was Actual or Near Miss  * A description of what happened or could have happened  * Actions taken to stabilize the patient including any examination by the physician,  ...  * The actions taken as a result of the event  ...  * Any other information that may be beneficial for others to know  ...  c) The patient's chart shall:  * Reflect all pertinent medical facts relating to the reportable event  * Appropriate facts shall be documented in the patient's medical record. The event report does not become part of the medical record. The fact that an
event report has been completed or the hotline was called shall not be documented in the patient's medical record. Entries made in the medical record related to the event contain only objective and factual information necessary for continuity of care. ... d) The patient's chart shall not: *State that an event report has been made; ... * Include comments or opinions of causation or potential liability. ... 4) Hospital Risk Manager or Designee Responsibilities a) The Hospital Risk Manager is responsible for: ... *Full oversight of the electronic event reporting system (eSRM), which includes but not limited to: * System Administrator Duties; ... - Ensuring all reported events from the prior month are closed no later the eighth day (8th) of the following month, with the exception of those under investigation. ... 5) Initial review and assessment of Event Reports a) The Risk Manager or designees shall be responsible for: ... *Determining whether the reportable event requires further action according to regulations and accreditation requirements - Report incidents and serious events under Pennsylvania Act 13 to the state via Pennsylvania Patient Safety Reporting
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

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<tr>
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STATE LICENSE NUMBER: 195601

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

| ID PREFIX | TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX | TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)
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System (PSRS). - Serious events must be reported to the Department of Health and the Pennsylvania Patient Safety Authority within 24 hours of the hospital's confirmation of the occurrence of the Serious Event. - Such reports shall be in the form and manner prescribed by the regulators ... - Incidents must be reported to the Pennsylvania Patient Safety Authority in a form and manner prescribed by the authority. ...

Review of a facility document, "May to Oct 15 Medication Events," dated May 1, 2015 through October 26, 2015, submitted to the Department on November 11, 2015, at 7:16 AM, from EMP1 revealed 342 medication events that included, but were not limited to, near misses, over doses, under dose, delays, drug omissions as a result of errors related to "ordering," "dispensing," "administration," and "documentation."

Review of correspondence submitted to the Department on November 11, 2015, at 7:16 AM, from EMP1 revealed documentation from EMP9 that indicated "... There was only one event that met
P 0317 Continued from page 20

the definition of a serious safety event and that event was reported to PSRS on the date of discovery which was 10/6/15. ... All of the other medication events are incidents. Due to an issue we are having with the interface between our safety reporting system (Quantros eSRM) and the PSRS system, those events have not yet been reported to PSRS. We have been working closely with our vendor and PSRS for many months now. We were very close to completing the interface in June 2015, but some of the PSRS fields were changed at that time. The Quantros team had to work to incorporate those changes in our software interface and mapping. The Quantros team is currently working with the PSRS team on the revised mapping and testing. Recent follow up has indicated that the work is almost completed and we hope to have the interface working very soon. ...

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1
"History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed "... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ..."

Further review of MR1 revealed no documentation pertaining to the two medication precipitating events that occurred prior to October 6, 2015 for the patient listed in MR1.

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be
Continued from page 22

re-accessed. EMP1 confirmed that this event was not yet reported but will be reported through PSRS. At 10:52 AM EMP10 indicated that all safety events are reported through Quantros and then get submitted through PSRS. At 10:52 AM EMP10 revealed that this was considered a safety event, and are reported through PSRS but that this was not submitted yet and that they were not up to date with PSRS submissions.

Further review of facility document, dated May 1, 2015 through October 26, 2015, that was submitted to the Department on November 11, 2015 revealed that the medication events that occurred on October 2 and October 4, 2015 for the patient listed in MR1 were not included on the document.

Interview on February 4, 2016, at 9:33 AM, with EMP10 confirmed that all "safety" events are submitted internally through "Quantros" and are then submitted through PSRS. At 9:37 AM, EMP9 indicated that "all serious events are reported manually within 24 hours." EMP9 indicated that the
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| P 0317        | Continued from page 23

The facility does report "near misses" as incidents.

Correspondence submitted to the Department, on February 11, 2016, at 11:39 AM, from EMP9 revealed that "incidents" have not been reported to PSRS due to a problem with the facility's electronic reporting system and PSRS. EMP9 indicated that "We had a call with our vendor Quantrios just this week and they have reported that they are not going to be able to resolve these issues until a new version is released, therefore we will need to enter all events in to PSRS manually. We are going to begin that process within the next two weeks."

The facility failed to report all reportable events through the Pennsylvania Patient Safety Reporting System.
# Statement of Deficiencies and Plan of Correction (POC)

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103.22 (b)(1) IMPLEMENTATION

(b) The following are minimal provisions for the Patient's Bill of Rights:

(1) The patient has the right to respectful care given by competent personnel.

This REGULATION is not met as evidenced by:

Policy & Procedures:
The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:

- Conduct a physician to physician or a physician to CRNP accuracy check prior to orders being written and sent to the pharmacy
- The Pharmacy staff will have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map
- use the revised Antineoplastic Drug Profile check list to document the verification process for orders
- document the independent double check completed by pharmacy staff and
- complete a record of who prepared the chemotherapy and who completed the double check of the
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PHILADELPHIA, PA  19134

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<td>P 0346</td>
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<td>chemotherapy that has been prepared. The Nursing Staff will require two chemotherapy certified (APHON) nurses to complete the double check process and document it so that a certified chemotherapy nurse may administer the chemotherapy. The revised policy was reviewed and approved at the Pharmacy and Therapeutics Committee on April 11, 2016. Training: The Director of Pharmacy or qualified designee educated all medical, pharmacy and nursing staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy and nursing employee education and annual re-orientation. Any physician who writes orders for chemotherapy will receive education on the policy as part of onboarding to the medical staff. The Chief Nursing Officer and the</td>
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The Director of Professional Development will offer a Chemotherapy Certification course to the nursing department to add additional nursing staff who will be chemotherapy certified. (APHON) Monitoring: The Director of Clinical Quality Improvement, the Director of Pharmacy or designees will monitor 100% of chemotherapy patient records concurrently for completion of the road map double checks, pharmacy verification process and nursing double check administration process. The monitoring process will include a review of patient records to ensure that only chemotherapy trained RN's administer and provide a double check related to chemotherapy are chemotherapy trained. The monitoring will continue until there is 100% compliance for 4 consecutive months. The information from monitoring will be reported to the hospital's Quality and Patient Safety Committee on a quarterly basis; and to the Medical Executive Committee and the
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| P 0346    |    | Continued from page 28                                | P 0346    |    | Governing Board quarterly for review and action as required.  
Responsible Person(s): Pediatrician-in-chief; Section Chief of Oncology; Chief Nursing Officer;  
Director of Pharmacy;  
Director Clinical Quality Improvement  
Quality and Patient Safety Committee  
Medical Executive Committee  
Governing Board  
Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.  
Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate. |
Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP) it was determined that the facility failed to ensure that nursing staff participating in the administration of chemotherapy medications were chemotherapy certified in accordance with facility policy for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Infusion Medication Administration (IMAR), Last Rev [review] Date: 10/12 [2012] Next Rev Date: 12/13 [2013]." revealed " I. POLICY: An infusion medication administration record will be maintained for every high-risk medication administration as an infusion. Every infusion will require an individual record. Two RNs will participate in the verification and documentation of these infusions. ... II. PERFORMED BY: 2 Registered Nurses III. DESIRED OUTCOME: In order to ensure accurate verification and documentation of all
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<td>P 0346</td>
<td>Continued from page 30 high-risk infusions, two RNs will participate in the verification and documentation of all high-risk infusions. ...&quot;. Review of facility policy &quot;Chemotherapy and Hazardous Medication Management,&quot; dated March 2014, revealed &quot;I. Policy&quot; A. Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ...these medications. ... Administration ... a. Chemotherapy is to be administered to the patient only by a chemo certified nurse in designated locations (...OTU,...) ...&quot;. Review of facility policy &quot;Chemotherapy Administration (Antineoplastic and Cytotoxic Drugs), dated February 2015, revealed &quot;I. Policy&quot; During preparation for chemotherapy administration, health care personnel, the patient and the environment will be protected from unnecessary</td>
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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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ST. CHRISTOPHER’S HOSPITAL FOR CHILDREN

**STATE LICENSE NUMBER:** 195601

**STREET ADDRESS, CITY, STATE, ZIP CODE:**
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PHILADELPHIA, PA 19134

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

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exposure to potentially hazardous substances. ... II. General Information A. Physician Orders: 1. ...Physician orders are required and must include the following information: protocol number, day, week, pre and post hydration orders, anti-emetics, drug, height, weight, Body Surface Area (BSA), dosage, route, diluent, administration frequency, and special precautions. ...C. Intravenous Infusion Chemotherapy: The following guidelines shall govern the administration of IV chemotherapeutic agents: ... 8. ... When using a Buretrol to administer medications, flush with appropriate agent between chemotherapy drug and medication. ... 13. Hourly assessment of peripheral and/or central venous access site is required during infusion of IV chemotherapeutic agents. During central line infusions, check dressing and chest wall every hour during chemotherapy administrations for signs of infiltration. ... 14. Hourly checks of infusion container, buretrol and pump settings should be completed and documented in the electronic record. 15. Special nursing consideration: *Etoposide (VP-16) and Teniposide (VM-26)* require the RN
to be present and monitor the administration of either of these drugs throughout the infusion ... III. PERFORMED BY: Registered Nurses: RN 's in the Oncology Unit, Oncology Clinic, and 5 West (Oncology Unit overflow) are required to be APHON Biotherapy Certified. ... VI. PROCEDURE: A. Preparatory Phase 1. Check physician ' s order, review BSA, check the label of all chemotherapy containers for patient ' s name, date, correct medication, dosage and diluent, expiration date and bottle number prior to infusion. This step needs to be independently double checked by another licensed practitioner and documented on the MAR. ... C. Follow-Up Phase ... 3. Document chemotherapy administration in the electronic record and EMR including the following information: location and type of line, chemotherapy dose, amount infused, sequence of drugs, type of flush solution and amount, description of infusion site, pre-medications, any reactions and/or interventions, responses, and indication that orders were double-checked. a. I/O Inet: Location and type of line, amount infused (chemotherapy), flush amount,
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- Description of infusion site, reactions and/or interventions, and responses.
- **b. EMR:** Pre-medications, chemotherapy dose, sequence of drugs, and type of flush, indication that orders were double-checked.  ""

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. "

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 m; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18, Witness: EMP20 10/3/2015 00:53; Verify: EMP18 ..."

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 4:03, revealed "Mesna 100..."
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mg 1 mL; d5nsh250 150 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP20 10/03/2015 04:03; Verify: EMP18 ...

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 12:28, revealed "Mesna d5i25 25 mL; mesn1i 100 mg 1 mL IV Chemo, Infusaport ... Perform: EMP8; Witness: EMP24 10/4/2015 12:28; Verify: EMP8 ...

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 12:52, revealed "Mesna mesn1i 100 mg 1 mL; d5i25 25 mL IV Chemo, Infusaport ... Perform: EMP25; Witness: EMP26 10/5/2015 12:52; Verify: EMP25 ...

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 00:55; Verify: EMP18 ...

Review of MR1 "Medication Administration," dated
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

(X) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307

(X2) MULTIPLE CONSTRUCTION:
A. BLDG: 00
B. WING: ______________

(X3) DATE SURVEY COMPLETED: 03/09/2016

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

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October 6, 2015, timed: 05:12, revealed "Ifex 500 mg+ Mesnex 100 mg ... IV Chemo, Infusaport ... Perform: EMP18 10/6/2015 03:08; Witness: EMP27 10/6/2015 03:08; Modify: EMP18 10/6/2015 05:11; Witness: EMP27 10/6/2015 05:11; Verify: EMP18 ... Result comment: EMP18 Chemo started late as port clotted and had to be reaccessed. ..."

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 04:32, revealed "Mesna ... IV Chemo, Infusaport ... Perform: EMP18; Witness: EMP23 10/6/2015 04:32; Verify: EMP18 ...

On January 26, 2016, at 3:33 PM, a request was submitted to EMP9 for documentation of specialized training in chemotherapy medications for the nurses who administered chemotherapy medication to the patient on October 2, 3, 4, 5, and 6.

Review of documents submitted to the Department,
Continued from page 36

on January 28, 2016, at 4:36 PM, by EMP9 revealed no documented evidence that EMP20 and EMP23, who participated in the administration and verification process of the administration of chemotherapy medications, were chemotherapy certified in accordance with facility policy.

Review of correspondence submitted to the Department, on February 11, 2016, at 11:39 AM, from EMP9 revealed that the facility does not "specify that the second professional must be APHON [Association of Pediatric Hematology/Oncology Nurses] Biotherapy certified."

On March 8, 2016, at 3:13 PM, another request containing a list of additional nurses who administered chemotherapy medication to the patient was submitted to EMP9.

Review of correspondence submitted to the Department, on March 9, 2016, at 12:42 PM, by EMP9, revealed that EMP24, EMP26 and EMP27,
who participated in the administration and verification process of the administration of chemotherapy medications, were not chemotherapy certified in accordance with facility policy.
103.22 (b)(7) IMPLEMENTATION

(7) The patient has the right to good quality care and high professional standards that are continually maintained and reviewed.

This REGULATION is not met as evidenced by:

Policy & Procedures: The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy.

Other Corrective Actions: The Director of Health Information and staff will assist the Oncology Department with the development of a standard template for all custom roadmaps. This roadmap template will include labeled space for the physician's signature, date and time as well as for the second verifying physician's signature and the date and time of verification of the roadmap. Literature used to develop custom roadmaps will be attached to the roadmap and scanned into the medical record. In addition, the literature will be supplied to the pharmacist preparing the chemotherapy. The Chief Nursing Officer and the Risk Manager will provide education to the Nursing Staff on the Charting.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
393307

(X2) MULTIPLE CONSTRUCTION:
A. BLDG: 00
B. WING: 

(X3) DATE SURVEY COMPLETED:
03/09/2016

STATE LICENSE NUMBER: 195601

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(X4) ID PREFIX TAG

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GUIDELINES POLICY AND PROCEDURE AND THE IMPORTANCE OF ACCURATE, COMPLETE AND THOROUGH DOCUMENTATION. THIS INCLUDES THE IMPORTANCE OF DOCUMENTING IN THE ELECTRONIC MEDICAL RECORD ALL UNUSUAL AND UNEXPECTED EVENTS AND OUTCOMES INCLUDING NOTIFICATIONS TO THE PHYSICIAN AND PHARMACY STAFF OF THOSE EVENTS.

TRAINING:
THE PHYSICIAN-IN-CHIEF SENT AN EMAIL TO ALL PHYSICIANS ON STAFF ON THE APPROPRIATE AND ACCURATE DOCUMENTATION REQUIRED IN THE MEDICAL RECORD INCLUDING THE REQUIREMENTS FOR AUTHENTICATION, DATING AND TIMING OF ALL ENTRIES. THE CHIEFS OF THE MEDICAL STAFF DEPARTMENTS WILL REVIEW THE EMAIL WITH THEIR DEPARTMENTS AT THEIR NEXT DEPARTMENT MEETINGS.

MONITORING:
THE ONCOLOGY DEPARTMENT WILL CONCURRENTLY MONITOR 100% OF THE DOUBLE CHECK VERIFICATION PROCESS INCLUDING AUTHENTICATION, DATING AND TIMING OF ROADMAPS BY BOTH THE AUTHOR AND THE VERIFIER. THE RESULTS

State Form

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IF CONTINUATION SHEET Page 40 of 111
### Statement of Deficiencies and Plan of Correction (POC)

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195601

#### Street Address, City, State, Zip Code:
160 EAST ERIE AVE
PHILADELPHIA, PA 19134

---

**Provided information continues from page 40.**

The Director of Health Information Management and staff will monitor medical records for completion of authentication, dating and timing. This information will be aggregated and reported to the Medical Staff Executive Committee at their routine meetings for review and action as required.

Responsible Person(s):
- Chief Nursing Office
- Risk Manager

[State Form]

[If Continuation Sheet Page 41 of 111]
P 0352 Continued from page 41

P 0352

Oncology Section Chief
Physician-in-Chief
Director Clinical Quality
Improvement
Director of Health Information
Management

Disciplinary Action:
Medical Staff members
demonstrating non-compliance with
corrective action will be referred for
peer review in accordance with
Medical Staff bylaws, as appropriate.
Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to provide and maintain good quality care and high professional standards for one of one medical record reviewed (MR1).

Findings include:

1. Review of facility policy "Rights and Responsibilities of Patients," dated January 14, 2014, revealed "I) Policy: 1) St. Christopher's Hospital for Children is committed to providing the best possible care to children and youth in a family-centered environment. ...  II) Patient Rights: Patients and/or parents or guardians acting on behalf of the patient have a right: ... 3) To provide considerate, respectful care given by competent personnel, including consideration of the psychosocial, spiritual and cultural variables that influence perception of illness. ... 18) To good quality care and high professional standards that are
<table>
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<tr>
<th>ID</th>
<th>Statement of Deficiencies and Plan of Correction (POC)</th>
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<tr>
<td>P 0352</td>
<td>Continued from page 43</td>
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</table>

continually maintained and reviewed. ...25) To expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient and family. The patient and the family have the right to expect reasonable safety insofar as hospital practices .... 

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed " ... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of cancer. Review of the "Roadmap" revealed " ... ICE
Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication] 1800 mg m^2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m^2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m^2/day (33mg/kg if age <1 yr) days 1-5. ... " The "Roadmap" revealed the following handwritten calculation for Etoposide "... 280 mg ..." 

Review of MR1 "Physicians' Orders," dated October 1, 2015, revealed "... Etoposide (33 mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hours at 50 cc/hr. Repeat 5 days. ..."

Review of MR1 "Medication Administration," dated October 2, 2015, timed: 00:52, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP19] 10/02/2015 00:52; Verify: [EMP18] ... ."

Review of MR1 "Nursing/Clinical Info," dated...
Continued from page 45

October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results wnl to begin chemo. 2315: Loading dose of zofran given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosfamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn given (abx compatible with Mesna per pharmacy). Mesna boluses to be given hrs 3, 9, 12. [Patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide
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<tr>
<th>ID PREFIX TAG</th>
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<td>P 0352</td>
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280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21]; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ...

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed 
"...01:00: Etoposide given over 2 hours via right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ...

Review of MR1 "Physician Progress Notes," dated...
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

**(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:** 393307

**(X2) MULTIPLE CONSTRUCTION:**
- A. BLDG: __________
- B. WING: __________

**(X3) DATE SURVEY COMPLETED:** 03/09/2016

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

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

**STATE LICENSE NUMBER:** 195601

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<tr>
<td>P 0352</td>
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<td>October 6, 2015, authenticated by EMP14, at 20:49, revealed &quot;This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ...&quot;</td>
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<td>P 0352</td>
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<td>Review of MR1 &quot;Discharge Summary,&quot; dated October 8, 2015, authenticated by EMP14, at 10:50, revealed &quot; ... Hospital Course: ONC</td>
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State Form 4LVR11

IF CONTINUATION SHEET Page 48 of 111
**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

<table>
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<th>(X4) ID PREFIX TAG</th>
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<td>P 0352</td>
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[Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ...RESIDENT A/P Assessment: ... After discovering the incorrect Etoposide dose, [the patient] was closely monitored. ... Patient is being closely monitored for possible liver, renal, bone marrow, neurologic, and respiratory damage secondary to potential Etoposide toxicity. Plan: Oncology: Completed chemotherapy 10/6 ... patient awaiting transfer to [another health care facility] on 10/6/2015. ...

Interview on January 11, 2016, at 10:00 AM, with EMP1 and EMP10 revealed that on October 6, 2015, EMP11, reviewed the dosing and concentration of Etoposide after being notified by EMP18 that the medication had precipitated during administration; EMP11 identified that the concentration/dose was too high.
Review of MR1 revealed no documented evidence that the physician was notified and assessed the patient during the two previous medication precipitating events that occurred prior to October 6, 2015. There was no documented evidence that pharmacy was notified.

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 revealed that a medication can precipitate if the concentration is too high or if there is not enough diluent. EMP1 confirmed that nursing is aware of what can cause a medication to precipitate. EMP1 confirmed that nursing did not document this event in the patient's medical record and revealed that nursing "documents by exception" meaning that "they document unusual occurrences." EMP1 confirmed that this event, involving the first occurrence of the Etoposide precipitating, was not reported to the Department or the Patient Safety Authority. At 10:59 AM EMP1 confirmed that there
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</table>
| P 0352        | Continued from page 50 was no documented evidence that the physician and/or pharmacy was notified of this event. EMP1 indicated that "most of the medication was administered by the time it was realized." Review of MR1 revealed no documented evidence regarding the exact amount of medication that the patient received during the first precipitating event that occurred on October 2, 2015 or the second precipitating event that occurred on October 4, 2015. 2. Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional
Continued from page 51

services were rendered to the patient. ... h) All entries in a patient's medical record shall be consistent and noncontradictory; information recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ...

Review of MR1 "Oncology Daily Progress Note," dated October 2, 2015, timed 14:01, authenticated by EMP14 on October 3, 2015 at 21:00, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ...

Review of MR1 "Physician Progress Notes," dated October 3, 2015, timed 01:11, authenticated by EMP14 at 20:59, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ...

Review of MR1 "Physician Progress Notes," dated October 4, 2015, timed 04:03, authenticated by EMP14, revealed " ... Plan: Oncology: ... -
etoposide 280 mg x 5 days ".

Review of MR1 "Physician Progress Notes," dated October 5, 2015, timed 19:56, authenticated by EMP14, revealed "... Plan: Oncology: ... - etoposide 280 mg x 5 days ".

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a
decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Interview on January 11, 2016, at 10:20 AM, with EMP1 indicated that a root cause analysis (RCA) was performed. EMP1 revealed that they didn't know why it took the facility five days to realize that there was an error with the dosage of Etoposide that was being provided to the patient in MR1. EMP1 indicated that the event was due to a "typographical" error made by EMP13. EMP1 indicated that four oncologists, EMP13, EMP14, EMP15 and EMP16, created the custom "Roadmap" to treat the patient's illness. EMP1 indicated that "the dose was to be 3.3 [mg/kg] not 33 [mg/kg] but EMP13 wrote down '33' instead of '3.3'" and then EMP17 transcribed the order based on what was written on the "Roadmap."

Review of MR1 "Physician Progress Notes" revealed that EMP14, who was involved in creating
# Statement of Deficiencies and Plan of Correction (POC)

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

**Completed Date:** 03/09/2016

---

## 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**

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## Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

<table>
<thead>
<tr>
<th>ID PREFIX  TAG</th>
<th>CLASSIFICATION</th>
<th>STATEMENT</th>
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<td>P 0352</td>
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<td>P 0934</td>
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The customized "Roadmap" to treat the patient's condition, repeatedly authenticated the incorrect dose: "etoposide 280 mg x 5 days."
### Statement of Deficiencies and Plan of Correction (POC)

**Name of Provider or Supplier:** ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN  
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**Identification Number:** 393307  
**Date Survey Completed:** 03/09/2016

### Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

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<th>ID Prefix Tag</th>
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#### 109.37 Unusual Incidents

A procedure shall be established to investigate any unusual incidents which occur at any time during any nursing shift. The procedure shall include the making and disposition of incident reports. Notation of incidents having a direct medical effect on a specific patient shall be entered in the medical record of that patient. Each report shall be analyzed and summarized, and corrective action shall be taken if necessary. Summarized reports shall be available to the Department.

This REGULATION is not met as evidenced by:

#### Policy & Procedures:

- The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards.
- No revisions were required to the policy.
- The Director of Risk Management reviewed the Event Reporting policy and procedure. No revisions were required to the policy.

#### Training:

- The Chief Nursing Officer and the Risk Manager educated the Pharmacy and Nursing staff on the Charting Guidelines policy and procedure and the importance of accurate, complete and through documentation. This included the importance of reporting all events, documenting all unusual or unexpected events; and outcomes related to medication administration in the electronic medical record and including the obligations to document notifications to physician and pharmacy staff in the electronic medical record.
### Monitoring:
The CNO and Director of Risk Management or designee will monitor the nursing documentation to ensure that all nursing and clinical information is included for chemotherapy administration and includes documenting all unusual or unexpected events; outcomes related to medication administration are included in the electronic medical record; and all notifications to physician and pharmacy staff are included in the electronic medical record. A quarterly report will be submitted to the Quality and Safety Committee for review and actions as required.

The Risk Manager monitors any reported events that are coded in the incident reporting system as a level D or above and checks to see if the documentation of the event is included in the patient's electronic medical record. This information will be included as trended data and reported to the Quality and Patient Safety Committee quarterly for
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<td>review for action as required.</td>
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<td>Responsible Person(s): Director of Professional Development Director of Risk Management Director of Clinical Quality Improvement Chief Nursing Officer Director of Pharmacy Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.</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

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STREET ADDRESS, CITY, STATE, ZIP CODE: 160 EAST ERIE AVE
PHILADELPHIA, PA  19134
Based on review of medical records (MR), review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to adequately document complications and unusual incidents in the medical record for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All entries in a patient's medical record shall be consistent and noncontradictory; information
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<td>Continued from page 59 recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ... 3) All atypical treatments shall be recorded with explanation as to why the treatments were rendered. a) All usual occurrences/incidents such as falls, medication errors, equipment malfunctions, and emergency situations shall be documented in the record. b) In all incidents, the recorder should objectively document only what was actually witnessed or observed. ... 5) The record must reflect ... physical condition, ... time physicians were notified, and the details of treatment ordered or rendered. ... 8) Physician, specialist, and consultant vitals to the patient and the professional services rendered shall be charted in the progress notes and on a consult form. 9) Documentation shall include: (i) Patient's ... responses to treatment .... 14) Charting must be objective and leave no room for conjecture, doubt, or misunderstanding of what is being recorded. .... &quot;</td>
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Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboxplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ""

Review of MR1 "Medication Administration," dated October 2, 2015, timed: 00:52, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP19] 10/02/2015 00:52; Verify: [EMP18] ... ."

Review of MR1 "Nursing/Clinical Info," dated October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results
Continued from page 61

wnl to begin chemo. 2315: Loading dose of zofran given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosfamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn given (abx compatible with Mesna per pharmacy). Mesna boluses to be given hrs 3, 9, 12. [Patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor.

Review of MR1 "Medication Administration," dated October 3, 2015, timed: 00:53, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP20] 10/03/2015 00:53; Verify: [EMP 18] ...

Review of MR1 "Nursing/Clinical Info," dated
### Statement of Deficiencies and Plan of Correction (POC)

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ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN

**State License Number:**
195601

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**Provider's Identification Number:**
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**Completed Date Survey:**
03/09/2016

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<td>P 0934</td>
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October 3, 2015, performed at 06:59, by EMP18 revealed "... 01:00: Etoposide given over 2 hrs via left chest port. ... Pt. tolerate well and no adverse reactions noted. ..."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ...

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] ...

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on
October 5, 2015.

Review of MR1 "Medication Administration," dated October 6, 2015, timed: 00:55, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP18] ; Witness: [EMP23] 10/04/2015 00:55; Verify: [EMP18] ...."

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed "...01:00: Etoposide given over 2 hours via right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ..."

Review of MR1 "Physician Progress Notes," dated
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<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DATE)</th>
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<td>P 0934</td>
<td>Continued from page 64</td>
<td>P 0934</td>
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October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed "... Hospital Course: ONC"
<table>
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<tr>
<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)</th>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>MULTIPLE CONSTRUCTION:</th>
<th>DATE SURVEY COMPLETED:</th>
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</thead>
<tbody>
<tr>
<td>ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN</td>
<td>393307</td>
<td>A. BLDG: 00</td>
<td>03/09/2016</td>
</tr>
<tr>
<td>STATE LICENSE NUMBER: 195601</td>
<td></td>
<td>B. WING:</td>
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<td>STREET ADDRESS, CITY, STATE, ZIP CODE:</td>
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<td>160 EAST ERIE AVE</td>
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<td>PHILADELPHIA, PA 19134</td>
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Continued from page 65

[Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ..."

Review of MR1 revealed a discrepancy in documentation as to when the patient's medication first precipitated. Review of MR1 revealed that the administration of Etoposide was initially administered on October 2, 2015.

Further review of MR1 revealed no documentation pertaining to the two medication precipitating events that occurred prior to October 6, 2015.

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 revealed that a medication can precipitate if the concentration is too high or if there is not enough diluent. EMP1 confirmed that nursing
is aware of what can cause a medication to precipitate. EMP1 confirmed that nursing did not document this event in the patient's medical record and revealed that nursing "documents by exception" meaning that "they document unusual occurrences." EMP1 confirmed that nursing should have documented this event in the patient's medical record. EMP1 confirmed that this event was not yet reported but will be reported through PSRS. EMP1 did not mention the medication precipitation event that occurred on October 4, 2015. At 10:52 AM EMP10 indicated that all patient safety events are reported through Quantros and then get submitted through PSRS. At 10:59 EMP1 indicated that "'most' of the medication was administered by the time it was realized."

Review of MR1 revealed no documented evidence regarding the exact amount of medication that the patient received during the first precipitating event that occurred on October 2, 2015 and the second precipitating event that occurred on October 4, 2015.
Review of facility document, dated May 1, 2015 through October 26, 2015, that was submitted to the Department on November 11, 2015 revealed that the medication events that occurred on October 2 and October 4, 2015 for the patient listed in MR1 were not included on the document.
113.1 GENERAL PROVISIONS - PRINCIPLE

113.1 Principle

The hospital shall provide for pharmaceutical services which are administered in accordance with accepted ethical and professional practices.

This REGULATION is not met as evidenced by:

Policy & Procedures:

The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:

The Pharmacy staff will:

- have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map;
- use the revised Antineoplastic Drug Profile check list to document the verification process for orders;
- document the independent double check completed by pharmacy staff and;
- complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy.

The Director of Pharmacy reviewed and revised the Pharmacy Antineoplastic Drug Profile Checklist. The checklist will be maintained in the patient's medication profile, and includes a
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<td>record of who prepared the chemotherapy, who completed the double check process, a checklist to ensure that a review of the road map was completed and compared to the written order, and access to the research the road map is based on.</td>
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Training:
The Director of Pharmacy or qualified designee educated all pharmacy staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy employee education and annual re-orientation. The Director of Pharmacy assigned all pharmacists who prepare chemotherapy to a chemotherapy training class. Pharmacists completed the class and passed a post training test. The chemotherapy class and post-test will become part of pharmacy annual re-orientation
The Director of Pharmacy educated all Pharmacy and Oncology Medical staff on the revised Pharmacy
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307

(X2) MULTIPLE CONSTRUCTION:
A. BLDG: __
B. WING: ________________

(X3) DATE SURVEY COMPLETED: 03/09/2016

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

DATE SURVEY COMPLETED: 03/09/2016

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

(X4) ID PREFIX TAG

P 1301 Continued from page 70

(X5) COMPLETE DATE

P 1301

Antineoplastic Drug Profile process to ensure that research materials are available for Pharmacy review.

Monitoring:
The Pharmacy Director will ensure that all staff preparing chemotherapy have received and successfully passed the chemotherapy training program. The records will be maintained in the staff personnel files.
The Director of Pharmacy will monitor that 100% of the custom road maps have the available research resources for pharmacy staff's reference; will monitor to ensure that there is a complete record of the documentation of the pharmacy chemotherapy double check that will be documented on the Antineoplastic Drug Profile check list that is maintained in pharmacy and includes the names of the two persons involved in the double check process of chemotherapy prepared in the pharmacy. (name of preparer and name of staff who completed the
### Pennsylvania Department of Health

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<td>double check). The audit results will be presented to the hospitals' Quality and Patient Safety Committee on a quarterly reporting schedule for review and action as required. Responsible Person(s): Director of Pharmacy Disciplinary Action: Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedure.</td>
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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**
Based on review of medical records (MR), review of facility policies and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that pharmaceutical services were provided in accordance with acceptable standards of practice and in accordance with facility policy for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Chemotherapy and Hazardous Medication Management," dated March 2014, revealed "I. Policy A. Special precautions will be taken whenever processing orders for cytotoxic drugs to minimize the possibility of a medication misadventure. B. All personnel will be familiar with the procedures for handling antineoplastic medications and follow them when preparing, dispensing, administering, ... these medications. ... II. Purpose Certain medications carry unique hazards. This policy promotes knowledge and understanding of these effects and how to mitigate them except as applied to patient
therapy. Policy will dictate the handling of these medications in a way that promotes better patient care and safety. IV. Procedure A. Chemotherapy. 2. Order processing, preparation and handling a. The pharmacist receiving the order (pharmacist #1) i. Will review the order for patient appropriateness and clarify the order with the ordering heme/one attending when necessary. ii. Will check the pertinent laboratory data. iii. Will enter the order into the computer to generate a patient charge and a label for the drug which includes: ... k) Initials of preparer and the checker ... iv. Must retrieve the patient chemotherapy profile in the Oncology Clinic (if it exists) or create a new patient folder and profile. ... b. Pharmacist #1 will complete the Pharmacy Drug Profile sheets for each drug in the order; Pharmacist #2 will verify the work. ... d. Each chemotherapeutic agent must be admixed individually by a pharmacy technician and all work checked by a pharmacist. i. Chemotherapeutic agents will be prepared by personnel specially trained in chemotherapy handling. ... e. Both pharmacists will retrieve and
### Multiple Construction

| A. BLDG: | 00 |
| B. WING: |    |

### Completed Date

03/09/2016

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<td><strong>St. Christopher's Hospital for Children</strong></td>
<td>P 1301</td>
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**Name of Provider or Supplier:**

**State License Number:** 195601

**State Address, City, State, Zip Code:**

160 East Erie Ave

Philadelphia, PA 19134

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**Summary Statement of Deficiencies (Each Deficiency Must be Preceded by Full Regulatory or LSC Identifying Information):**

- review the label, the order, and the patient profile; then review admixing instructions with the pharmacy technician utilizing package inserts and other references needed. f. Prior to having a certified chemo technician complete the preparation of products, the pharmacist will call a second pharmacist (pharmacist #2) to check the following: i. The original orders against the printed label and all calculations ii. The original orders against the protocol and roadmap (chemotherapy profile) ... g. ... vi. The preparer will affix the prepared label and precautionary labels to the final product and indicate completeness by initialing the chemotherapy profile.
- h. The pharmacist witnesses the technician completing the preparation, initials the label, and initials the chemotherapy profile. ... j. The patient chemotherapy order form will be placed in the chemotherapy file for future reference. ...

Review of facility policy "High Risk Medications Management (High Alert)," dated March 2014, revealed "I. Policy SCHC will develop and maintain a list of High Risk Medications. Medications and
medication classes on this list will be subject to greater control due to the high potential for errors or consequences of errors. II. Purpose To outline processes for defining, communicating, and enforcing medication management safety measures to promote safe use of high alert high risk medications and reduce medication errors and their consequences. III. Procedure A. Definitions 1. High risk medications: Medications that bear heightened risk of causing significant patient harm when used in error (Institute for Safe Medication Practice ISMP). … B. Processes will be in effect at every stage of medication management that relates to high risk medication use. … 3. Prescribing/Transcribing … c. Dose range checking is utilized in both PowerChart CPOE and PharmNet. d. When high risk medications are ordered by the provider using an alternative to CPOE, e.g., chemotherapy protocols … , the relevant orders will be transcribed by the pharmacist into PharmNet and thus into the eMar and PowerChart. e. Down time handling of orders will include double check by the pharmacist of all high risk medication orders and adherence to
downtime policies for nursing and providers. 4. Preparation/Dispensing a. Independent double check by the person who prepares the high risk medication and a second person (one of who must be a licensed pharmacist) are mandatory. ...".

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient’s rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication]1800 mg m2/dose (60
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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

**DATE SURVEY COMPLETED:** 03/09/2016

**NAME OF PROVIDER OR SUPPLIER:**
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mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr Cl, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ...

Etoposide [chemotherapy medication] 100 mg/m2/day (33mg/kg if age <1 yr) days 1-5. ...

The "Roadmap" revealed the following handwritten calculation for Etoposide "... 280 mg ...

Review of MR1 "Physicians' Orders," dated October 1, 2015, revealed "... Etoposide (33 mg/kg) or 280 mg IV diluted in 100 cc NS to be infused over 2 hours at 50 cc/hr. Repeat 5 days. ...

Review of MR1 "Orders," dated October 1, 2015, revealed "... Etoposide ... Order Details: 280 mg=14 mL, Injection, IV Chemo, ... Pharmacist Verify Electronically Signed, EMP12 on 10/1/2015 16:10 ...

Review of MR1 "Nursing/Clinical Info," dated October 6, 2015, performed at 04:55, by EMP18 revealed "...01:00: Etoposide given over 2 hours via..."
right chest port. Towards middle to end of infusion, pump kept beeping occluded, port flushed with heparin, + blood return, but the last 5 cc of flush unable to be given as port clotted off. Port then had to be reaccessed. ... Spoke to pharmacy as chemo precipitated [deposited in solid form from a solution] in line on Sat [Saturday] morning. Per pharmacy, dose is highly concentrated because of pt. weight and this is causing the precipitate which then clotted the port. ...

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is
10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Review of MR1 "Discharge Summary," dated October 8, 2015, authenticated by EMP14, at 10:50, revealed " ... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including ... Etoposide ... The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse. ... RESIDENT A/P Assessment: ... After discovering the incorrect Etoposide dose, [the patient] was closely monitored. ... Patient is being closely monitored for possible liver, renal, bone marrow, neurologic, and respiratory damage secondary to potential Etoposide toxicity. Plan:
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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Oncology: Completed chemotherapy 10/6 ... patient awaiting transfer to [another health care facility] on 10/6/2015. ...

Interview on January 11, 2016, at 10:00 AM, with EMP1 and EMP10 revealed that EMP12 and EMP31 prepared and dispensed the Etoposide on October 2, 2015 but they were unsure as to who prepared and dispensed the Etoposide on October 3, 4, 5, and October 6, 2015. EMP1 indicated that pharmacy only verifies the order once for a "multiple fill order," they do not complete the full verification process on each day the medication is being prepared and dispensed. EMP1 indicated that the pharmacists receive the order and check it with the "Roadmap" and then verify the dose.

Review of correspondence submitted to the Department, on January 28, 2016, at 4:22 PM, from EMP9 revealed that the facility did not have record as to which pharmacists actually prepared and dispensed Etoposide each day. EMP9 indicated that the pharmacist signs the label after it is printed,
but then the label is discarded once the medication is finished.

There was no documented evidence that pharmacy reviewed the physician's order for accuracy and appropriateness, nor completed the verification and check process, in accordance with facility policy.

The facility failed to ensure that pharmaceutical services were provided in accordance with acceptable standards of practice and in accordance with facility policy.
### Statement of Deficiencies and Plan of Correction (POC)

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

**Date Survey Completed:** 03/09/2016

**State License Number:** 195601

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

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#### Summary Statement of Deficiencies

**ID Prefix Tag:** P 1304

- **Continued from page 82**

113.3 (b) **Pharmacist**

113.3

(b) The pharmacist shall be trained in the specialized functions of hospital pharmacy.

This REGULATION is not met as evidenced by:

- Policy & Procedures:
  - The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following:
    - The Pharmacy staff will have access to the literature related to the research resources related to the chemotherapy ordered on the custom road map, use the revised Antineoplastic Drug Profile check list to document the verification process for orders; document the independent double check completed by pharmacy staff and complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy.
  - The Director of Pharmacy reviewed and revised the Pharmacy Antineoplastic Drug Profile Checklist. The checklist will be maintained in the patient's medication profile, and includes a...
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<td>P 1304</td>
<td>Continued from page 83</td>
<td>P 1304</td>
<td>record of who prepared the chemotherapy, who completed the double check process, a checklist to ensure that a review of the road map was completed and compared to the written order, and access to the research the road map is based on.</td>
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Training:
The Director of Pharmacy or qualified designee educated all pharmacy staff on the revised policy related to Chemotherapy and Hazardous Medication Management. This information has been included in new pharmacy employee education and annual re-orientation. The Director of Pharmacy assigned all pharmacists who prepare chemotherapy to a chemotherapy training class. Pharmacists completed the class and passed a post training test. The chemotherapy class and post-test will become part of pharmacy annual re-orientation. The Director of Pharmacy educated all Pharmacy and Oncology Medical staff on the revised Pharmacy.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

- **IDENTIFICATION NUMBER:** 393307
- **MULTIPLE CONSTRUCTION:**
  - A. BLDG: __
  - B. WING: __
- **DATE SURVEY COMPLETED:** 03/09/2016

**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

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<td>P 1304</td>
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<td></td>
<td>Antineoplastic Drug Profile process to ensure that research materials are available for Pharmacy review.</td>
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<td>Monitoring:</td>
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<td>The Pharmacy Director will ensure that all staff preparing chemotherapy have received and successfully passed the chemotherapy program. The records will be maintained in the staff personnel files.</td>
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<td>The Director of Pharmacy will monitor that 100% of the custom road maps have the available research resources for pharmacy staff's reference. The audit results will be presented to the hospitals' Quality and Patient Safety Committee on a quarterly reporting schedule for review and action as required.</td>
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<td>Responsible Person(s): Director of Pharmacy</td>
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<td>Disciplinary Action: Non-compliance with corrective action by hospital staff will result in</td>
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<td>Immediately remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.</td>
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State Form 4LVR11
Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that all pharmacists engaging in the preparation and dispensing of chemotherapy medications received specific training in order to provide quality services, maintain competency and meet the needs of the patient population being served for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Rights and Responsibilities of Patients," dated January 14, 2014, revealed "I) Policy: 1) St. Christopher's Hospital for Children is committed to providing the best possible care to children and youth in a family-centered environment. ... II) Patient Rights: Patients and/or parents or guardians acting on behalf of the patient have a right: ... 3) To provide considerate, respectful care given by competent personnel, including consideration of the psychosocial, spiritual and cultural variables that
influence perception of illness. ... 18) To good quality care and high professional standards that are continually maintained and reviewed. ...25) To expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient and family. The patient and the family have the right to expect reasonable safety insofar as hospital practices ....”

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed " ... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was
Continued from page 88

developed to treat the patient’s rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2... Wt. 8.6 kg... Ifosfamide [chemotherapy medication] 1800 mg/m²/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication] 360 mg/m²/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m²/day (33mg/kg if age <1 yr) days 1-5. ... " The "Roadmap" revealed the following handwritten calculation for Etoposide "... 280 mg ..."

Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M² per day."
The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Interview on January 11, 2016, at 10:13 AM, with EMP10 revealed that the "'normal chemo' pharmacist, [EMP4]," was not working during the time Etoposide was prepared and dispensed to the patient in MR1. EMP10 revealed that the pharmacists who prepared and dispensed the Etoposide don't frequently prepare chemotherapy medications. EMP1 indicated that the pharmacists are not certified in chemotherapy medication preparation and that there is no facility policy that requires it. EMP1 revealed that these pharmacists
"have been here for years but that they received training during orientation on pediatric dosing and mixing chemotherapy medications." EMP10 revealed that as a result of the medication error, involving Etoposide, the pharmacist working in oncology will rotate as to who prepares chemotherapy medications in order to maintain competency.

On January 26, 2016, at 9:03 AM, a request was submitted to EMP9 for a list of the actual pharmacists who prepared and dispensed Etoposide on October 2, 3, 4, 5, and October 6, 2015. EMP9 was also asked for a copy of their last training/education that each pharmacist received regarding chemotherapy pharmacy.

Review of correspondence submitted to the Department, on January 28, 2016, at 4:22 PM, from EMP9 revealed that the facility did not have record as to which pharmacists actually prepared and dispensed Etoposide each day. EMP9 indicated that the pharmacist signs the label after it is printed,
but then the label is discarded once the medication is finished. EMP9 revealed that there are no specialized educational requirements or oncology specific requirements that are required of the pharmacists in order to work in oncology. EMP9 indicated that "... pharmacists orient with [EMP4] in the oncology clinic checking and verifying orders and learning the process involved until they feel that they can handle clinic and chemotherapy admissions. This is usually a 3 to 6 month period depending on if they have any prior experience. "

The facility failed to ensure that all pharmacists engaging in the preparation and dispensing of chemotherapy medications received specific training in order to provide quality services, maintain competency, and meet the needs of the patient population being served.

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<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<td>P 1304</td>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

(XI) PROVIDER/SupPLiER/CLIA IDENTIFICATION NUMBER: 393307

(X2) MULTIPLE CONSTRUCTION:
A. BLDG: __
B. WING: ________________

(X3) DATE SURVEY COMPLETED: 03/09/2016

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

(X4) ID PREFIX TAG

| IDPREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | IDPREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE
| COMPLETE DATE |
|--------------|-------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------|
| P 1525       | Continued from page 92                                                                                                        | P 1525       | Policy & Procedures: The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy. The Director of Pharmacy and the Chief Nursing Officer reviewed the policy and procedure on Medication Monitoring to ensure it meets current standards of practice. No revisions to the policy were required at this time. The Director of Pharmacy and the Chief Nursing Officer reviewed and revised the policy and procedure 30.16 Chemotherapy and Hazardous Medication Management to include the following: The Oncology medical staff will: use a double checks process for the road map for each individual patient conduct a physician to physician or a physician to CRNP accuracy check prior to orders being written and sent to the pharmacy. The Pharmacy staff will: have access to the literature related
|               |                                                                                                                          | Completion Date: 05/06/2016 | Status: APPROVED Date: 04/28/2016 |

115.32 (a) CONTENTS

115.32 Contents
(a) The medical record shall contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately.

This REGULATION is not met as evidenced by:
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

**(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:**

| 393307 |

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PHILADELPHIA, PA 19134

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

**ID PREFIX TAG**

| P 1525 | Continued from page 93 |

| P 1525 | to the research resources related to the chemotherapy ordered on the custom road map; use the revised Antineoplastic Drug Profile check list to document the verification process for orders; document the independent double check completed by pharmacy staff and; complete a record of who prepared the chemotherapy and who completed the double check of the chemotherapy that has been prepared. The Nursing Staff will require two chemotherapy certified (APHON) nurses to complete the double check process and document it so that a certified chemotherapy nurse may administer the chemotherapy. The revised policy was reviewed and approved at the Pharmacy and Therapeutics Committee on April 11, 2016 Training: The Chief Nursing Officer and the Risk Manager educated the Nursing staff on the Charting Guidelines |

**ID PREFIX TAG**

P 1525

**COMPLETE DATE**

| (X5) COMPLETE DATE |

Pennsylvania Department of Health
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)**

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**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

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<td>policy and procedure and the importance of accurate, complete and through documentation. This included the importance of documenting all unusual or unexpected events and outcomes related to medication administration in the electronic medical record and including the obligations to document notifications to physician and pharmacy staff in the electronic medical record. The Director of Pharmacy or qualified designee educated all medical, pharmacy and nursing staff on the revised policy related to Chemotherapy and Hazardous Medication Management. Monitoring: The Director of Pharmacy or designee reviews 100% of the chemotherapy orders using the Pharmacy Antineoplastic Drug Profile as a source document. This information is reported to the Quality and Patient Safety Committee quarterly for review and action as required. The Risk Manager monitors any reported events that</td>
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<td>P 1525</td>
<td>are coded in the incident reporting system as a level D or above and checks to see if the documentation of the event is included in the patient's electronic medical record. The medical record will be reviewed to ensure the medical record contains nursing/clinical information during chemotherapy infusions; ensure the medical record contains unusual occurrences/incidents; documentation of the notifications to physicians and pharmacists of unusual occurrences/incidents and to ensure the roadmap is a part of the patient's medical record. This information will be included as trended data and reported to the Quality and Patient Safety Committee quarterly for review and action as required</td>
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Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to ensure that necessary information was included in a patient's medical record in order to adequately monitor a patient's condition and provide appropriate care for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All entries in a patient's medical record shall be
consistent and noncontradictory; information recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ... 3) All atypical treatments shall be recorded with explanation as to why the treatments were rendered. a) All unusual occurrences/incidents such as falls, medication errors, equipment malfunctions, and emergency situations shall be documented in the record. b) In all incidents, the recorder should objectively document only what was actually witnessed or observed. ... 5) The record must reflect ... physical condition, ... time physicians were notified, and the details of treatment ordered or rendered. ... 8) Physician, specialist, and consultant vitals to the patient and the professional services rendered shall be charted in the progress notes and on a consult form. 9) Documentation shall include: (i) Patient's ... responses to treatment ... . 14) Charting must be objective and leave no room for conjecture, doubt, or misunderstanding of what is
### Statement of Deficiencies and Plan of Correction (POC)

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

**Date Survey Completed:** 03/09/2016

**Provider/Supplier:** ST. CHRISTOPHER’S HOSPITAL FOR CHILDREN

**State License Number:** 195601

**Street Address, City, State, Zip Code:** 160 EAST ERIE AVE, PHILADELPHIA, PA 19134

### Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

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Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ..."

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient’s rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide [chemotherapy medication]1800 mg m2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication]360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication]..."
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Review of MR1 "Nursing/Clinical Info," dated October 2, 2015, performed at 06:19, by EMP18 revealed "Nursing Note: 7p-7a: Received pt. at 2030 from 5w. NGT feeds started per home regime at 2030. 55mls/hr for a total of 660mls. Retching once overnight and small emesis around 5:30. Feeds held at small intervals. UA obtained and sent, results wnl to begin chemo. 2315: Loading dose of zofran given. 2400: Carboplatin given via left chest port over one hour. 0100: VP-16 [another name for Etoposide] given over 2 hours. BP's checked Q15 min and remained stable. 0300: Ifosfamide [sic] given over one hour. + blood return pre/during/post chemo. 0400: 3 hour Mesna infusion started. 0415: Temp 38.4 MD [physician's name] informed and evaluated. Dr. [EMP15] informed. Per MD orders bld cx's x 2 obtained, tylenol given, tobra and zosyn given (abx compatible with Mesna per pharmacy).
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

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| P 1525    |     | Continued from page 100  
Mesna boluses to be given hrs 3, 9, 12. [Patient's parent] attentive at bedside, pt. resting comfortably, will continue to monitor."

Review of MR1 "Medication Administration," dated October 4, 2015, timed: 00:33, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:33; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 4, 2015.

Review of MR1 "Medication Administration," dated October 5, 2015, timed: 00:47, revealed "Etoposide 280 mg 14 mL; ns100 100 mL IV Chemo, Infusaport ... Perform: [EMP21] ; Witness: [EMP22] 10/04/2015 00:21; Verify: [EMP21] ... ."

Review of MR1 revealed no "Nursing/Clinical Info" documentation during the infusion of Etoposide on October 5, 2015.
Review of MR1 "Physician Progress Notes," dated October 6, 2015, authenticated by EMP14, at 20:49, revealed "This morning I was notified of a severe medication error involving the VP-16 (Etoposide) that [Patient] had received for the past 5 days. It was found to be a typographic error on the custom roadmap lead to a dose of 33 mg/kg/day per dose instead of the 3.3 mg/kg/day per dose based on the typical dosing of 100mg/M2 per day. The VP-16 was already finished when the error was discovered. ... due to the error [patient] received the above noted dose of Etoposide (VP-16). This is 10x the daily dose we intended for [patient]. ... I was very concerned that this error could have severe, life threatening and used the word lethal consequences. ... I explained that this was due to a decimal error on the custom roadmap. ... I told [patient's parent] that it was my responsibility as the Section Chief. ... They assured [patient's parent] that an exhaustive review of this would occur. ..."

Review of MR1 "Discharge Summary," dated
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

#### PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

- **State Form**

#### MULTIPLE CONSTRUCTION:

- **A. BLDG:** __
- **B. WING:** __

#### COMPLETED DATE

- **03/09/2016**

#### STATE LICENSE NUMBER:

- **195601**

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

#### STREET ADDRESS, CITY, STATE, ZIP CODE:

- **160 EAST ERIE AVE**
- **PHILADELPHIA, PA 19134**

#### SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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October 8, 2015, authenticated by EMP14, at 10:50, revealed "... Hospital Course: ONC [Oncology]: Completed 2nd cycle of chemotherapy per protocol, including Etoposide. The Etoposide precipitated on 10/1, 10/4, and 10/6 due to the highly concentrated dose of medication administered, requiring frequent line flushes per nurse."

Interview on January 11, 2016, at 10:30 AM, with EMP1 revealed that the medication precipitated on October 2, 2015, that caused the patient "temporary harm," and that the site had to be re-accessed. EMP1 confirmed that nursing did not document this event in the patient's medical record.

Further review of MR1 revealed no documentation regarding the medication precipitating event that occurred on October 4, 2015.

Interview on February 4, 2016, at 9:00AM, with EMP9 revealed that EMP13 typed the customized "Roadmap."
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Interview on February 4, 2016, at 9:09 AM, with EMP10 revealed that literature was used to develop the patient's treatment protocol, the customized "Roadmap." EMP10 revealed that the literature was not included in the patient's chart nor was it sent to pharmacy to allow for pharmacy to review with the "Roadmap" prior to filling the orders. EMP10 revealed that the literature used to develop customized "Roadmaps" would "sometimes" be sent to pharmacy, "but not always." EMP10 revealed that the facility did not have an established policy for this process.

The facility failed to ensure that necessary information was included in a patient's medical record in order to adequately monitor a patient's condition and provide appropriate care.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

| (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | 393307 |
| (X2) MULTIPLE CONSTRUCTION: | A. BLDG: __
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<td>P 1532</td>
<td>Policy &amp; Procedures: The Director of Health Information Management reviewed the Charting Guidelines policy and procedure to ensure it meets current standards. No revisions were required to the policy. Other Corrective Actions: The Director of Health Information and staff will assist the Oncology Department with the development of a standard template for all custom roadmaps. This roadmap template will include labeled space for the physician's signature, date and time as well as for the second verifying physician's signature and the date and time of verification of the roadmap. Literature used to develop custom roadmaps will be attached to the roadmap and scanned into the medical record. In addition, the literature will be supplied to the pharmacist preparing the chemotherapy. Training: The Physician-in-Chief sent an email</td>
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<td>to all physicians on staff on the appropriate and accurate documentation required in the medical record including the requirements for authentication, dating and timing of all entries. The Chiefs of the Medical Staff departments will review the email with their departments at their next department meetings. Monitoring: The Oncology Department will concurrently monitor 100% of the double check verification process including authentication, dating and timing of roadmaps by both the author and the verifier. The results will be reported quarterly to the Quality and Patient Safety Committee. The Director of Health Information Management and staff will monitor medical records for completion of authentication, dating and timing. This information will be aggregated and reported to the Medical Staff Executive Committee at their routine meetings for review and action as necessary.</td>
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Based on review of medical records (MR), review of facility policy and procedures and interview with staff (EMP), it was determined that the facility failed to ensure all entries in the medical record were dated and authenticated by the person making the entry for one of one medical record reviewed (MR1).

Findings include:

Review of facility policy "Charting Guidelines, Medical Records," dated October 25, 2012, revealed "I) POLICY: To ensure that St. Christopher's Hospital for Children has medical records that are clear and legible; the following charting guidelines shall be forwarded by all staff that has responsibility for documenting patient care and/or status. II) PROCEDURE: ... d) Each entry shall be signed by the individual making the entry. ... f) Documentation shall record precisely what was stated, observed, or reported and what professional services were rendered to the patient. ... h) All entries in a patient's medical record shall be
### Continued from page 108

consistent and noncontradictory; information recorded in one section of the record must be consistent with information recorded in other locations. i) All entries shall be read before countersigning. Countersignature attests to the authenticity of what has been written. ...

Review of MR1 "History and Physical," dated October 1, 2015, revealed that the patient was admitted to the hospital's OTU for inpatient chemotherapy treatment. Further review of MR1 "History and Physical" revealed "... 1. Oncology: Admit for ICE chemotherapy: carboplatin x 1 day, ifosamide/etoposide x 5 days with mg/kg dosing as [patient] is < [less than] 1 year old. ...

Review of MR1 revealed a customized "Roadmap" (a treatment protocol that contains a list of medications and dosing information to be utilized to treat a patient's specific condition) that was developed to treat the patient's rare form of cancer. Review of the "Roadmap" revealed "... ICE Courses: cycles 2 ... Wt. 8.6 kg ... Ifosamide
Continued from page 109

[chemotherapy medication]1800 mg m2/dose (60 mg/kg/dose if age <1 yr) days 1-5; Mesna [chemotherapy medication]360 mg/m2/dose (12 mg/kg if age <1 yr) x 5 doses: 1st dose in bag with Ifos. Dose 2 over 3 hr CI, doses 3-5 at hr 3, 6, 9. Give 100% mesna. ... Etoposide [chemotherapy medication] 100 mg/m2/day (33mg/kg if age <1 yr) days 1-5. ..." The "Roadmap" revealed the following handwritten calculation for Etoposide " ...284 ... 280 mg ..." Further review of the "Roadmap" revealed that the document was not dated, nor was it authenticated by the individual who transcribed the "Roadmap" and performed the calculations contained on the "Roadmap."

Interview on February 4, 2016, at 9:24 AM, with EMP9 confirmed that the "Roadmap" document, contained in MR1, was not dated nor was it authenticated. EMP9 indicated that the document should have been authenticated and dated.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)

<table>
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<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 393307</th>
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</thead>
<tbody>
<tr>
<td>(X2) MULTIPLE CONSTRUCTION:</td>
</tr>
<tr>
<td>A. BLDG: <strong>00</strong>____</td>
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<tr>
<td>B. WING: ________________</td>
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<tr>
<td>(X3) DATE SURVEY COMPLETED: 03/09/2016</td>
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</table>

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)

<table>
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<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)</th>
<th>(X5) COMPLETE DATE</th>
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<td>P 1532</td>
<td>Continued from page 110</td>
<td>P 1532</td>
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</tbody>
</table>
Certified End Page

ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN
STATE LICENSE NUMBER: 195601
SURVEY EXIT DATE: 03/09/2016

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Christine C. Filipovich, MSN, RN
Deputy Secretary For Quality Assurance

Karen M. Murphy, PhD, RN
Secretary of Health

THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY