Accepted OK RB 3/10/14 jw

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OMB NO. 0938-0391

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	053301	A. BUILDING _____ B. WING _____	C 01/10/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHILDREN'S HOSPITAL & RESEARCH CENTER OAKLAND	747 52ND STREET OAKLAND, CA 94609

(X4) 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 DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during a Complaint Validation Survey conducted on 1/7/14 through 1/10/14. The patient census on entrance was 151. Representing the Department: Medical Consultant 20340, Health Evaluator Supervisor 25632, and Health Facilities Evaluator Nurses 25205, 25206, 16538 and 32427. The following Conditions of Participation were reviewed: Governing Body, Patient Rights, Nursing Services, Surgical Services, and Anesthesia Services. The hospital was in substantial compliance with the Conditions of Participation reviewed. There was one deficiency identified for Surgical Services.	A 000	The statements made in this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein. This Plan of Correction constitutes Children's Hospital & Research Center of Oakland's written credible allegations of compliance for the deficiencies noted. RECEIVED MAR 07 2014 Licensing & Certification East Bay District Office	
A 951	482.51(b) OPERATING ROOM POLICIES Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. This STANDARD is not met as evidenced by: Based on interview and record review the hospital failed to ensure that the policy and procedure to complete the "Passport to Surgery/ Procedure Pre-Operative Checklist" was done for 8 Patients (18, 14, 15, 32, 33, 34, and 38) of 29 patients reviewed, resulting in the potential of	A 951	In accordance with hospital policy and procedures, Medical Staff Rules and Regulations section 21.9 and regulatory requirements, history and physical examinations and consents to surgery are present in the medical record prior to surgery. Surgical Services policies governing surgical care are developed, maintained and reviewed at required intervals by Surgical Services Hospital and Medical Staff Leadership as well as appropriate surgical services staff. In accordance with the Peri-operative Services policy "Preoperative Assessment and Reassessment". The pre-operative check list is utilized to ensure all relevant documentation such as (history and physical examinations, consent to surgery, labs and other necessary data) is in the Electronic Medical Record (EMR) prior to surgery. For inpatients, the pre-operative check list is completed before a patient is transported to the operating room. In some cases, records are not electronic and are in paper form, such as history and physicals. All paper documents remain with the patient in the mini-chart and are forwarded to HIM for scanning subsequent to the procedure or at discharge.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
	V.P. Institutional Quality & Family Support Services	March 4, 2014

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 951	Continued From page 1	A 951		

incomplete assessments for Patients 18,14, 32, 33, 34, and 38 by not having a History and Physical in the record prior to going to the operating room and a potential for violation of patients' rights for Patients 14,15, 33 and 34 by not having a consent for surgery/procedure in the record prior to going to the operating room.

Findings:

Review on 1/10/14 of the "Preoperative Assessment and Reassessment" policy dated and revised 11/11 showed that the policy instructed staff that the collected data is used to make judgment and predictions about a patient's response to illness or changes in life process and to identify nursing diagnoses and predict outcomes and that the registered nurse is responsible for ensuring that the preoperative assessment is complete. The policy instructed that the pre-op checklist is utilized to ensure all relevant documentation such as history and physical, consent, labs and all necessary data is in the passport to surgery before a patient is transported to the operating room. The policy further instructed that patients who are deemed ready for surgery must have all required elements on the surgery check-off list or an explanation of why the list is not complete, before transport to the operating room.

1. Review of the medical record on 1/10/14, showed that the hospital admitted Patient 18 for care on 1/10/14. Patient 18 was a 5 year old boy who came to the hospital for surgery on his left eye for cataract removal and intraocular lens implant (a patient's cloudy natural lens is removed and replaced with a synthetic lens to restore the lens's transparency).

The Preoperative checklist dated 1/10/14 at 6:46 a.m., showed that the Pre-op RN-1 (Registered Nurse) documented that the history and physical

OR Leadership recognized Pre-Op Check List documentation inconsistencies on 1/9/2014 following recent implementation of our EMR which occurred 11/5/2013.

At the time of surgery, and during the CMS Survey, all required elements of the record were present and available in the medical record in accordance with hospital policy despite the incomplete documentation noted in the EMR. Audit results and observations revealed, all required elements were present in the medical record prior to surgery.

On 1/9/2014 it was identified that the pre-op checklist was inconsistently completed due to an electronic mapping error of the required data elements as well as a staff education deficiency. When OR leadership recognized these issues, the following were implemented:

1. OR Leadership identified inconsistencies with staff knowledge and EMR Reports summarizing the completion of the pre-op checklist. 1/9/2014

2. A workgroup was developed consisting of EMR Analysts, OR Leadership, and pre-op staff to outline the corrective action needed to improve the documentation on the Pre-op checklist. 1/9/2014

3.EMR Build Team initiated changes to the EMR pre-op check list to address the report mapping errors and to make it easier for staff to complete the required elements of the Pre-op Checklist. 1/10/2014

Continued on next page.

V.P. Institutional Quality & Family Support Services

March 4, 2014

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A 951	Continued From page 2 was "not on chart" and "OR RN notified" (OR RN is the operating room registered nurse.) 1/10/14 at 9:15 a.m., review of the record with the (electronic record specialist for the recovery room) EPIC PACU RN showed no History and physical by the surgeon in the record and that Patient 18 had been taken to the Operating room at 8:49 a.m. The EPIC PACU RN stated that there were two places that the OR RN could have charted that the history and physical was in the record, by updating the Pre-op checklist and by filling out the "Sign In Time Out" but neither had been done. Further review of the record on 1/10/14 at 12 p.m. showed that the History and physical had been scanned into the EPIC system at 11:01 a.m., after the surgery. On 1/10/14 at 2 p.m., during an interview, OR RN 2 stated that he had been notified by the pro-op nurse that there was no history and physical in the record, but that this surgeon never entered the history and physical into EPIC (the electronic record) that this surgeon always brought the history and physical with him to the operating room and placed the hand written form into the record and that it was later scanned into the electronic record. OR RN 2 stated he did not document anywhere in the record that the History and physical was not in the record prior to the patient being taken to the operating room. On 1/10/14 at 2:20 p.m., during an interview, the ADPS (Assistant Director of Perioperative Services) stated that the expectation is that if there is no History and physical in the record there should be a "Hard Stop" and the patient would not go the operating room until it was completed and on the record. The ADPS explained that there were three "Time Outs" that the OR RN is supposed to fill out in the electronic	A 951	Continued from page 2 4. OR and PACU Assistant Directors initiated immediate education for pre-op and OR staff regarding the need to complete EVERY field of the pre-op check list that is in the EMR to ensure a complete report for the Pre-op Checklist. 5. Daily chart audits were initiated to validate the effectiveness of initial education. Feedback to staff was provided, as needed for the chart audit results. 6. EMR Build Team completed changes to the EMR pre-op check list, to make it easier for staff to complete the required elements. 7. The OR leadership team validated that OR staff education was completed regarding for the revised workflow to facilitate completion of the pre-op checklist. 8. The Perioperative Services Preoperative Assessment and Reassessment Policy was updated to add information about the purpose of the pre-op check list, the required elements, and updating the pre-op checklist as the patient progresses through the pre-op process. 9. Ongoing monitoring of pre-op checklist completion was added to the surgical services quality dashboard. OR and PACU assistant directors ensure that at least 50 audits per month are completed to validate compliance with the Preoperative Services Preoperative Assessment and Reassessment policy.	1/10/2014 1/10/2014 - 1/17/2014 1/17/2014 1/17/2014 1/20/2014 2/20/2014

V.P. Institutional Quality & Family Support Services

March 4, 2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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A 951	Continued From page 3 record. The first is a "Sign In time out that address the pre op check list consent, history and physical and labs etc.; the second is the "Pre-incision Time Out" that is done right before incision checking with all staff in the operating room that they are doing the correct procedure to the correct patient on the correct site with the correct equipment; and the third is the "Sign-Out Time Out" that addresses the post op assessment, sponge and sharp counts etc. The ADPS stated that these time outs were presented in educational inservices to all perioperative staff and that the expectation is that all three will be filled out for each patient. 2. Clinical record review of the form called "Passport to Surgery/ Procedure Pre-Procedural Checklist" for Patients 14 and 15 did not show completion prior to surgery. The consent, history and physical and laboratory results were not checked off as completed for Patients 14, and there was no documentation that a follow up was done for surgical checklist completion prior to the surgical procedure. Furthermore, the surgical checklist indicated that the consent was not signed for Patient 15, and there was no documentation that a follow up was done for surgical checklist completion prior to the surgical procedure. 3. On 1/9/14 and 1/10/14, review of the electronic medical record, EPIC (Electronic Privacy Information Center) showed a form titled, "Passport to Surgery/ Procedure Pre-Procedural Checklist." For Patients 32, 33 and 38 there was no documentation on the pre-surgical checklists to reflect the date and time that the histories and physicals were completed by a nurse on the surgical ward, in the pre-operative area or in the operating room prior to the surgical procedures.	A 951	Answer below corresponds to findings 2 - 5 At the time of surgery, and during the CMS Survey, all required elements of the record were present and available in the medical record in accordance with hospital policy. It was noted, however, that the pre-op checklist was inconsistently documented due to an electronic mapping error of the required data elements, as well as, a staff education deficiency regarding the workflow. The following were implemented to address these issues: 1. OR Leadership identified inconsistencies with staff knowledge and EMR Reports summarizing the completion of the pre-op checklist. 2. A workgroup was developed consisting of EMR Analysts, OR Leadership, and pre-op staff to outline the corrective action needed to improve the documentation on the Pre-op checklist. 3. EMR Build Team initiated changes to the EMR pre-op check list to address the report mapping errors and to make it easier for staff to complete the required elements of the Pre-op Checklist. 4. OR and PACU Assistant Directors initiated immediate education for pre-op and OR staff regarding the need to complete EVERY field of the pre-op check list that is in the EMR to ensure a complete report for the Pre-op Checklist. 5. Daily chart audits were initiated to validate the effectiveness of initial education. Feedback to staff was \provided, as needed for the chart audit results. 6. EMR Build Team completed changes to the EMR pre-op check list, to make it easier for staff to complete the required elements. 7. The OR leadership team validated that OR staff education was completed regarding for the revised workflow to facilitate completion of the pre-op checklist. Continued on next page	1/9/2014 1/9/2014 1/10/2014 1/10/2014 1/10/2014 - 1/17/2014 1/17/2014 1/17/2014

V.P. Institutional Quality & Family Support Services

March 4, 2014

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A 951	Continued From page 4 4. For Patients 33 and 34 there was no documentation on the pre-surgical checklists to reflect the date and time that any nurse confirmed that the consents for surgery were present in the charts. In separate interviews with Nurse Manager 1, on 1/9/14 at 1:30 p.m., and Director 1, on 1/10/14 at 10:45 a.m.; both stated that the patients' pre-surgical checklists should be completed prior to the surgical procedures. If the checklist wasn't completed prior to the patients going to surgery then the operating room RN had the responsibility for reviewing and documenting in the checklist that the history and physical and consent were in each medical record. 5. In addition there were items left blank on the checklists for Patients 32, 33, 34, and 38. For instance, Patient 33 had a blank space next to the checklist item: "Time of last breastmilk." Patient 33 was 9 years old and not breastfeeding. At 10:45 a.m., Nurse Manager 1 further stated that if the items in the pre-operative checklist were not applicable then the nurse should document "N/A" on the form and not leave it blank.	A 951	Continued from page 4 Answer corresponds to finding 2-5 8.The Perioperative Services Preoperative Assessment and Reassessment Policy was updated to add information about the purpose of the pre-op check list, the required elements, and updating the pre-op checklist as the patient progresses through the pre-op process. 9. Ongoing monitoring of pre-op checklist completion was added to the surgical services quality dashboard. OR and PACU assistant directors ensure that at least 50 audits per month are completed to validate compliance with the Preoperative Services Preoperative Assessment and Reassessment policy. The statements made in this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein. This Plan of Correction constitutes Children's Hospital & Research Center of Oakland's written credible allegations of compliance for the deficiencies noted.	1/20/2014 2/20/2014

V.P. Institutional Quality & Family Support Services

March 4, 2014

JR.

CHILDREN'S HOSPITAL
& RESEARCH CENTER OAKLAND

March 5, 2014

Nancy Casazza
Licensing and Certification
East Bay District Office
850 Marina Bay Parkway, Bldg. P, 1st Floor
Richmond, CA 94804

Re: Response to Complaint Number CA00380468

Ms. Casazza,

Enclosed please find CMS 2567 Statement of Deficiencies and Plan of Correction as it relates to complaint number CA00380468.

If you need further information, please contact Carolyn Dossa 510-450-7656 or e-mail cdossa@mail.cho.org. Shannon Bardwell at 510-428-3885 ext. 4803 or e-mail sbardwell@mail.cho.org.

Sincerely,

Richard DeCarlo, Executive V.P. & Chief of Hospital Operations

cc:
Primary Contact: Carolyn Dossa, V.P. Institutional Quality & Family Support Services

747 Fifty Second Street • Oakland, CA 94609-1809
(510) 428-3000
www.childrenshospitaloakland.org

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707
(415) 744-3696

CENTERS FOR MEDICARE & MEDICAID SERVICES

February 18, 2014

CMS Certification Number: 05-3301

Bertram Lubin, M.D.
Chief Executive Officer
Children's Hospital and Research Center at Oakland
747 52nd Street
Oakland, CA 94609

Dear Dr. Lubin:

On January 10, 2014, the California Department of Public Health (CDPH) completed a complaint validation survey authorized by the Centers for Medicare & Medicaid Services (CMS). CDPH determined that Children's Hospital and Research Center-Oakland was in compliance with the Medicare Conditions of Participation (CoPs). However, the enclosed survey report (Form CMS-2567) document standard deficiencies were cited.

Since your hospital has been determined to be in compliance with the all applicable Conditions of Participation, you do not have to submit a plan of correction for any of the standard deficiencies. However, under Federal disclosure rules, a copy of the findings of this Medicare complaint survey will be made available to the public upon request. You may therefore choose to submit for public disclosure, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

Should you choose to submit a plan for correction, the evidence of correction is to be entered on the right side of the Form CMS-2567, opposite the deficiencies, and must be signed and dated by the administrator or other authorized official. Please submit your evidence of correction to this CMS San Francisco office **and** the CDPH-East Bay office by close of business, within ten (10) days of receipt of this letter.

The evidence of correction of each item must contain the following:

1. How the correction was accomplished, both temporarily and permanently, including any system changes that were made.

2. The title or position of the person responsible for correction, i.e., Administrator, Director of Nursing or other responsible supervisory personnel.

3. A description of the monitoring process to prevent recurrences of the deficiency, the frequency of the monitoring and the individual(s) responsible for the monitoring.

4. The date when correction of the deficiency was accomplish.

We have forwarded copies of this letter to the Joint Commission and CDPH.

If you have any questions about this matter, please contact Gina Brown of my staff at (415) 744-2931.

Sincerely,

Rufus Arther, Manager
Non-Long Term Care Survey, Certification
& Enforcement Branch

Enclosure: Form CMS-2567