Cleveland Clinic

Joseph F. Hahn, MD
Chief of Staff

November 5, 2013

VIA ELECTRONIC MAIL AND OVERNIGHT DELIVERY

Ms. Tamra Swistowicz
Non-Long Term Care Certification & Enforcement
Division of Survey and Certification
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, IL 60601-5519

Re: *Cleveland Clinic (CCN 36-0180)*

Dear Ms. Swistowicz:

Accompanying this letter please find a plan of correction ("**PoC**") prepared by Cleveland Clinic (the "**Hospital**") in response to the statement of deficiencies related to a resurvey conducted at the Hospital which concluded September 26, 2013.

The Hospital appreciates the opportunity to provide the enclosed PoC identifying its corrective action plans in relation to the issues identified during the survey.

If you have any questions, or if we can provide you with any additional information to assist in your review of the PoC, please contact Eileen Pomiecko, Senior Director, Accreditation, at 216-445-8400 or at pomiece@ccf.org.

Sincerely,

Joseph F. Hahn, M.D.
Chief of Staff

Enclosures

cc: Wanda Iacovetta, Ohio Department of Health
The Joint Commission, Office of Quality Monitoring

The Cleveland Clinic Foundation

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Cleveland, Ohio 44195

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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
	360180	A. BUILDING _____ B. WING _____	R-C 09/26/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CLEVELAND CLINIC	9500 EUCLID AVENUE CLEVELAND, OH 44195

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECED BY FULL REGULATORY OR LSC IDENTIFIED 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 Post-Survey Revisit to Complaint Survey completed on July 25, 2013. The following deficiencies are re-cited based on the post-survey revisit completed on September 26, 2013.	{A 000}	**TAG A000:** Cleveland Clinic Hospital (the "Hospital") is committed to providing safe and quality care, treatment and services to all patients. In order to maintain this commitment to our patients, the Hospital has policies, guidelines, and committees in place that help guide, monitor and strengthen our patient care activities and compliance obligations with the goal of ensuring that the Conditions of Participation are met throughout the hospital. This written Plan of Correction was prepared in response to a Form 2567 received from the Centers for Medicare and Medicaid Services on 10/22/2013.	
{A131}	482.13(b)(2) PATIENT RIGHTS:INFORMED CONSENT The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This STANDARD is not met as evidenced by: RECITED Based on electronic medical record review and interview, the facility failed to obtain general consent on admission as required by the facility's policy for six (Patient #1, #2, 1/3, 1/5, #7 and #9) of eleven electronic medical records reviewed for general consents. This had the potential to affect all of the facility's patients. The facility's active census at the time of the survey was 1040 patients. Findings include: 1. The electronic medical record review for	{A 131}	**TAG A131** Corrective Action Patient Access Services (PAS) Director reviewed the General Consent Procedure and determined an opportunity to revise the procedure to improve clarity and direction including: - additional direction on documenting attempts on the general consent form, specifically regarding authorized representatives, refusals and the requirement for scanning with each update - clarification on best efforts regarding: expired patients, discharged within 48 hours and adults presenting to EDs, etc who are unable to consent. The revised procedure will be presented for approval by the BOG/MEC and Board Policy Committee on or before 11/13/2013. The job aid for obtaining general consents will be updated to reflect procedural changes by 11/20/2013.	11/23/13

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Chief of Staff — (X6) DATE: 11/5/13

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 131}	Continued From page 1 Patient #1 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The electronic medical record contained a signed general consent form on 09/24/13, three days after admission. The document did not contain documentation of attempts made by the PAS (Patient Access Services) to obtain the consent prior to 09/24/13. On 09/26/13 at 9:46 AM, these findings were confirmed by Staff J. 2. The electronic medical record review for Patient #2 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The electronic medical record contained a signed general consent form on 09/24/13, three days after admission. The document included documentation the PAS had made one attempt to obtain consent on 09/22/13, the day after the date of admission. On 09/26/13 at approximately 9:30 AM, the findings were confirmed by Staff J. 3. The electronic medical record review for Patient #3 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The electronic medical record contained a signed general consent form on 09/24/13, three days after admission. The document did not contain documentation of attempts made by the PAS to obtain consent prior to 09/24/13. On 09/26/13 at approximately 9:30 AM, the findings were confirmed by Staff J. 4. The electronic medical record review for	{A 131}	**Tag A131 continued** The Director and Senior Director of Patients First Support Services (PFSS) designed a leadership model to provide oversight and support for all shifts. Changes include an on-site manager, additional work leaders to support 16/7 coverage, 3rd shift on call and up staffing. FTE count will increase from 18.2 to 25.9 by 2/2014. Interim leadership has been in place effective 9/26/2013 as well as upstaffing with overtime. Educational Efforts: Interim PAS manager and supervisor conducted remediation training with all (PAS) staff through staff meetings and one-on-one discussions on or before 10/4/ 2013. Continuing education is provided as issues and opportunities are identified. Any full or part time staff member that is on paid time off or other leave of absence will be required to complete the training upon returning to work. Additional education will be provided regarding date/time documentation and relationship to patient when the patient does not sign. This training will be completed by 11/23/ 2013. As part of the daily compliance review, employees not following the procedure will be provided counseling, feedback and ongoing education on their next work shift Feedback and follow up can include corrective action as appropriate. Compliance Monitoring: - Daily, including weekends, the PAS, senior manager, manager, supervisor, work leader and quality monitoring specialist will monitor compliance with the procedure to ensure 90% compliance for hospital inpatients, through the daily incomplete registration work list report.	

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{A 131}	Continued From page 2 Patient #5 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The record contained a signed general consent form dated 09/24/13, three days after the date of admission. The document did not contain documentation of attempts made by the PAS to obtain the consent prior to 09/24/13. On 09/26/13 at 9:46 AM, the findings were confirmed by Staff J. 5. The electronic medical record review for Patient #7 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The record contained a signed general consent form dated 09/24/13, three days after admission. The document contained documentation the PAS had made one attempt to obtain consent on 09/22/13, one day after the date of admission. On 09/26/13 at approximately 9:30 AM, the findings were confirmed by Staff J. 6. The electronic medical record review for Patient #9 was completed on 09/26/13 at 9:46 AM. The patient was admitted to the facility on 09/21/13. The record contained a signed, but undated general consent form. On 09/26/13 at approximately 9:30 AM, Staff J confirmed without a date on the consent form it could not be determined when the general consent had been obtained. On 09/26/13 at 8:59 AM, the facility's General Consent Procedure was reviewed. The procedure stated the PAS will make up to three attempts within 48 hours of admission to obtain consent	{A131}	**Tag A131 continued** - A second report, the 24-hour report, allows for focused follow up. All incomplete general consents are identified on the 24-hour report and either signature is obtained or the number of required attempts are made and documented per procedure in the final 24 hours of the 48-hour compliance window. Daily compliance results are shared with the Sr. Director and Executive Director of Revenue Cycle Management (RCM). The monthly performance is recorded on the PFSS monthly scorecard and presented by the Sr. Director to the Executive Director and Chief Financial Officer as part of the monthly update. Ultimately, the Sr. Director of RCM is responsible for compliance with this Tag.	

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{A 131}	Continued From page 3 signature. Each attempt should be documented on the consent form with the date and time. Signed and dated consent forms or consent forms with documented attempts to obtain the consent will be scanned into the electronic medical record under the administrative document type. On 09/25/13 at 4:10PM, Staff J was interviewed. Staff J reported the facility had a Patient Access Services staff member call off work for a twelve hour shift on 09/21/13. He/she reported several phone calls were made unsuccessfully in an attempt to cover the 12 hours shift. Staff J reported he/she became aware of the missed shift approximately one hour ago. On 09/26/13, Staff J was interviewed from 9:26 AM to 10:00 AM. He/she reported the facility increased the PAS staffing on 09/23/13 and 9124/13 in an effort to obtain general consents from patients who were admitted on 09/21/13. Staff J reported the Patient Access Services staff members continues to utilize an old form for the documentation of attempts made to obtain general consent. Staff J stated he/she has reinforced with the PAS staff members the need to have the attempts for obtaining consent documented on the consent form. Staff J provided a list of patients admitted who had not signed general consent forms. The list contained two patients with an admission date of 09/21/13. Staff J reported the PAS staff members do not scan the general consent forms into the electronic medical record until the consent has been obtained. He/she provided examples of general consent forms in which the PAS attempts for consent had been documented.	{A 131}		

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{A 951} {A 951}	Continued From page 4 482.51 (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: RECITED Based on interview, electronic medical record review, policy review, and observation, the facility failed to follow the facility's surgical counts policy on completing a final count at the completion of surgery for one (Patient #13) of two final surgery counts observed and one (Patient #14) of eight electronic medical records reviewed for surgical counts. This had the potential to affect all surgery patients. Findings include: 1. On 09/26/13 at 2:25 PM, an observation of a trabeculectomy (a surgical procedure to treat glaucoma) surgery for Patient 1/13 was conducted. At approximately 2:35 PM, Staff A and Staff H were observed completing a relief count as required by the facility's policy. At approximately 2:45 PM, Staff H announced a final suture needle count to Staff A, who was standing across the room, and was unable to visualize the	{A 951}	**TAG A951** Corrective Actions The "Count Policy" and associated "Count Procedure", approved by the Governing Body on 8/14/2013, were reviewed by the Senior Director for Surgical Nursing and were found to be sufficient; however an opportunity for re-education was identified. To provide consistent oversight and to improve communication, accountability and compliance, on 9/30/2013, there was a change in reporting structure so that the Cole Eye Operating Rooms now report to the Senior Director of Nursing for Surgery. Educational Efforts On 10/16/2013, the Cole Eye Nursing staff was re-educated by the Assistant Nursing Director for Surgery, Education and Professional Development of the Count Policy and Count Procedure. The in-person in-service specifically emphasized the sections of the policy mandating that "All items must be audibly counted and concurrently viewed as they are separated and counted by two individuals, one of whom must be a registered nurse" along with the importance of final count documentation. An in-person inservice will be held on 11/22/2013 for Cole Eye surgeons to reemphasize their role in the count process.	10/16/13

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{A 951}	Continued From page 5 On 09/26/13 at approximately 3:00 PM, Staff C, Staff D, and Staff E confirmed they had not observed Staff A visualize the final count for Patient #1. On 09/26/13 at 3:30 PM, the patient's procedure report was reviewed. The report had documentation of an initial count, a relief count, and final count as having been conducted. 2. The electronic medical record review for Patient #14 was completed on 09/25/13. The record showed the patient had undergone surgery on 09/23/13, for strabismus repair (eye muscle surgery). The procedure report contained documentation of an initial count, and a relief count. The report did not contain documentation a final count had been completed. The findings were confirmed by Staff F on 09/25/13 at 11:00 AM. On 09/25/13 at 1:04 PM, Staff I reported he/she had spoken with Staff A and Staff B regarding the undocumented final count. Staff I stated Staff A and Staff B reported they had completed a final count on the patient but forgot to document the final count. On 09/25/13 at 11:23 AM, the facility's Counts Policy was reviewed. The policy stated all items must be audibly counted and concurrently viewed as they are separated and counted by two individuals. The counts will occur prior to commencing the procedure (initial count), when the scrub and\or circulator is permanently relived (relief count) and during skin closure (final count).	{A 951}	**Tag A951 continued** Compliance Monitoring Beginning 10/23/2013, the Nurse Manager, Quality Nurse and assigned staff will conduct monthly audits for compliance with the existing policy and procedure. Audits will continue until 90% compliance is achieved for a period of 3 consecutive months. Results will be reported to the Surgical Operations Executive Committee and Cole Eye Institute Administration for individualized follow-up as needed. The Senior Director of Surgical Nursing has ultimate responsibility for this Tag.	