Lakewood Hospital
a Cleveland Clinic hospital

Shannan D. Ritchie
Interim President, Lakewood Hospital

February 4, 2015

Mr. Brian Dean
Assistant Chief
Bureau of Regulatory Compliance
246 N. High Street, 3rd Floor
Columbus, Ohio 43215

RE: Lakewood Hospital, Adult Cardiac Catheterization Lab HCS – OHCS00066
Lakewood Hospital, Open Heart Surgery HCS – OHCS00066
Ordered Plan of Correction for Lakewood Hospital Health Care Services

Dear Mr. Dean:

On behalf of Lakewood Hospital (the "Hospital"), accompanying this letter please find the Plan of Correction ("POC") prepared by the Hospital in response to the Statement of Deficiencies document received from your office on January 26, 2015. The attached POC responds to issues raised during the Ohio Department of Health ("ODH") survey completed on August 6, 2014.

The Hospital looks forward to resolving these issues with ODH. If you have any questions, or if we can provide you with any additional information regarding the enclosed POC, please contact Mary Kirsch, Accreditation Manager, at 216-529-7428.

Sincerely,

Shannan D. Ritchie
Interim President

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	OHCS00066	A. BUILDING: _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LAKEWOOD HOSPITAL	14519 DETROIT AVENUE CLEVELAND, OH 44107

(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) COMPLETE DATE
H 000	Initial Comments Health Care Services Inspection County: Cuyahoga Administrator: Mr. Shannan Ritchie, Interim Director Services: Open Heart surgery Capacity: Two operating rooms designated for open heart surgeries The following violations were issued as a result of the Health Care Services Inspection completed on 08/06/14.	H 000	Tag H000 Lakewood 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 Ohio Administrative Code rules for Adult Cardiac Catheterization and Open Heart Surgery are met. This written Plan of Correction was prepared in response to a State Form received from the Ohio Department of Health on January 26, 2015.	
H 361	3701-84-36 (C) Open Heart Surgery - 24 Hour Emergencies (C) The provider of an open heart surgery service shall have the capability, equipment, and personnel to perform twenty-four hour emergency open heart procedures. A cardiovascular surgical team shall be available in less than sixty minutes on a twenty-four hour basis. This STANDARD is not met as evidenced by: Based on observation, staff interview and facility documentation review the facility failed to utilize the required on site adult open heart surgical suite or maintain qualified staff on the facility's cardiovascular surgical staff roster. This deficient practice had the potential to negatively effect any patients who might require open heart surgery. The facility transferred 10 patients in the previous 12 months who received a cardiac catheterization	H 361	Tag H361 **Corrective Action/Policy Changes:** On January 27, 2015, Hospital Administration and Physician Leadership conducted a review of the open heart surgical and high-risk catheterization programs. As a result of the review and confirmation that no open heart surgery had taken place at the Hospital since 2007, the Hospital will no longer offer high-risk cardiac catheterizations, coronary interventions or open heart surgery as of February 25, 2015. **Educational Efforts:** The Medical Executive Committee will be informed of this decision at its meeting on February 2, 2015. Members of the Cardiology Department will be informed at the next Department meeting which will occur on or before February 25, 2015. Other relevant staff, including Nursing, Emergency Department personnel and EMS services will be informed on or before February 25, 2015.	2/25/2015

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H 361	Continued From page 1 at the facility and then required open heart surgery . Findings include: 1. Review of the facility's documentation entitled Fairview and Lakewood Hospitals Scope of Service, Operations, and Standards of Care Protocol - Invasive Cardiology, with a last approved date of 08/06/13, directed on page 2 of the seven page document that Selected Criteria for Identifying High Risk Conditions for Cardiac Catheterization: patients with high risk conditions listed below may require emergency catheter-based therapeutic interventions or open heart surgery. Hence, they shall undergo cardiac catheterization only in a catheterization laboratory that has an open heart surgical support available on site (i.e. accessible from the catheterization laboratory by gurney.) 2. Tour of the facility's two open heart suites conducted on the morning of 08/04/14 revealed the facility had two fully equipped operating rooms dedicated for open heart surgery and the necessary heart lung bypass machines which were fully operational. Interview with Staff A at the time of the tour verbalized the suites were always kept ready. 3. Review of the facility's documentation entitled Cardiac Catheterization Patients to FV (Fairview Hospital) for Cardiac Surgery documented 10 patients were transferred to the facility's sister hospital at Fairview for open heart surgery following cardiac catheterization procedures performed at Lakewood Hospital. The documentation further revealed the facility had transferred 34 patients between January 2012 and July 2014.	H 361	Tag H361 (Contd.) **Monitoring of Compliance:** Medical Director for Cardiovascular Services is ultimately responsible for ongoing compliance with this tag.	

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H 361	Continued From page 2 4. Review of facility staff documentation revealed the facility failed to staff any open heart surgical staff other than two X-Ray technicians on staff. The records further indicated the dedicated and qualified cardiac open heart surgical team for the facility were in fact, all on their sister facility's (Fairview Hospital) staff roster. Additionally, all the staff's personnel records and training records were maintained at the sister facility as well. 5. Interview with Staff B on 08/04/14 at 11:17 A.M. Staff B revealed the Cleveland Clinic enterprise had designated that Fairview Hospital was the site for all open heart surgeries. 6. Patients who underwent cardiac catheterization at Lakewood Hospital and required subsequent open heart surgeries were all transferred to Fairview for cardiac surgery. Staff B confirmed the two facilities maintained different Health Care Facility identification numbers. Staff B further confirmed the entire cardiovascular open heart surgical team with the exception of two X-Ray technicians were not on staff at Lakewood Hospital. Staff B confirmed all cardiovascular surgical team members were on staff at Fairview Hospital. 7. Interview with Staff A on 08/05/14 at 1:05 P.M. confirmed the facility performed 276 cardiac catheterizations in the past twelve months, but the last open heart surgery performed in this facility was seven years ago on 11/05/2007. 8. All patients who required open heart surgery were transferred to Fairview Hospital for open heart surgery. Staff A confirmed 10 patients who received cardiac catheterization at the facility were transferred from the Lakewood Hospital	H 361		

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H 361	Continued From page 3 facility to Fairview Hospital for open heart surgery in the previous 12 months.	H 361		
H 370	3701-84-37 (A) Open Heart Surgery - Medical Director (A) The medical director of the adult open heart surgery service shall be board certified in an appropriate specialty. The medical director shall be: (1) Responsible for oversight of care in the service; (2) Credentialed to provide adult open heart surgery services at the hospital where he or she is the medical director; and (3) Actively performs open heart procedures at the hospital where he or she is the medical director. This STANDARD is not met as evidenced by: Based on facility documentation and staff interview the facility's medical director failed to perform any open heart surgeries at the facility in the preceding twelve months. This deficient practice had the potential to negatively effect any patients who sought open heart surgical procedures at the facility. The facility discharged and transported ten patients who required open heart surgery to another facility in the previous 12 month period. Findings include: Review of the facility's documentation revealed the facility director failed to perform any open heart surgical procedures for the previous twelve	H 370	Tag H370 **Corrective Actions:** See response for Tag H361 **Educational Efforts/Policy Changes:** N/A **Monitoring of Compliance:** N/A	2/25/2015

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H 370	Continued From page 4 months to current date of 08/06/14. The last open heart surgical procedure performed by at the facility by the medical director was on 11/05/2007. Interview with Staff A on on 08/05/14 at 12:17 PM confirmed the facility has failed to perform any open heart surgeries since 2007. Staff A verbalized all patients who were diagnosed at the facility's cardiac catheterization laboratory and recommended for open heart surgery were then discharged from the facility and transported to another facility for open heart surgery procedures.	H 370		
H 372	3701-84-37 (C) Open Heart Surgery - Qualified Staff (C) The provider of an open heart surgery service shall have competent and qualified staff available, including but not limited to: (1) Surgical assistants to assist the surgeon. A surgical assistant may be a resident, another physician, a registered nurse first assistant, or a specially trained surgical assistant; (2) Cardiac anesthesiologists with special training in the anesthetic and supportive requirements of open heart surgery; (3) Nursing staff which shall include appropriate numbers of scrub nurses or technicians and circulating nurses or technicians. A minimum of one scrub nurse and one circulating nurse is necessary. Nursing staff shall be trained in cardiac surgical operating room procedures; (4) Cardiac surgical intensive care unit shall be	H 372	Tag H372 **Corrective Action/Policy Change:** See Response for Tag H361 **Educational Efforts:** N/A **Monitoring of Compliance:** N/A	2/25/2015

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H 372	Continued From page 5 staffed at the appropriate nurse patient ratio commensurate with the acuity of the patients and the amount of time following surgery that such care is necessary. Cardiac surgical intensive care nurses shall have specialized training to develop the theoretical knowledge and clinical skills required for the care of cardiac surgical patients; and (5) A minimum of two perfusionists. Perfusionists shall be graduates of an approved circulation technology training program or have equivalent training and experience. This STANDARD is not met as evidenced by: Based on observation, staff interview and facility documentation the facility failed to utilize the required on site adult open heart surgical suite or maintain qualified staff on the facility's cardiovascular surgical staff roster. This deficient practice had the potential to negatively effect any patients who might require open heart surgery. The facility transferred ten patients who received cardiac catheterization at the facility and who further required open heart surgery in the previous 12 months. Findings include: Review of the facility's documentation entitled Fairview and Lakewood Hospitals Scope of Service, Operations, and Standards of Care Protocol - Invasive Cardiology with a last approved date of 08/06/13 directed on page 2 of the seven page document that Selected Criteria	H 372		

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H 372	Continued From page 6 for Identifying High Risk Conditions for Cardiac Catheterization: patients with high risk conditions listed below may require emergency catheter-based therapeutic interventions or open heart surgery. Hence, they shall undergo cardiac catheterization only in a catheterization laboratory that has an open heart surgical support available on site (i.e. accessible from the catheterization laboratory by gurney.) Tour of the facility's two open heart suites conducted on the morning of 08/04/14 revealed the facility had two fully equipped operating rooms dedicated for open heart surgery and the necessary heart lung bypass machines which were fully operational. Interview with Staff A at the time of tour verbalized the suites were always kept ready. Review of the facility's documentation entitled Cardiac Catheterization Patients to FV (Fairview Hospital) for Cardiac Surgery documented 10 patients were transferred to the facility's sister hospital at Fairview for open heart surgery following cardiac catheterization procedures performed at Lakewood Hospital. The documentation further revealed the facility had transferred 34 patients between January 2012 and July 2014. Review of the facility staff documentation revealed the facility failed to staff any adult open heart surgical staff other than two X-Ray technicians on staff. The records further indicated the dedicated and qualified cardiac open heart surgical team for the facility were in fact, all on their sister facility's (Fairview Hospital) staff roster. Additionally, all the staff's personnel records and training records were maintained at the sister facility as well.	H 372		

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H 372	Continued From page 7 Interview with Staff B on 08/04/14 at 11:17 A.M. Staff B verbalized that the Cleveland Clinic enterprise had designated that Fairview Hospital was the site for all open heart surgeries. Patients who underwent cardiac catheterization at Lakewood Hospital and required subsequent open heart surgeries were all transferred to Fairview for cardiac surgery. Staff B confirmed the two facilities maintained different Ohio health Care Facility inspection numbers. Staff B further confirmed that the entire cardiovascular open heart surgical team with the exception of two X-Ray technicians were not on staff at Lakewood Hospital or its corresponding Ohio Healthcare Services Licensure number currently being inspected. Staff B confirmed all cardiovascular surgical team members were on staff at Fairview Hospital. Interview with Staff A on 08/05/14 at 1:05 P.M. confirmed the facility performed 276 cardiac catheterization in the past twelve months but the last open heart surgery performed in the facility was seven years ago on 11/05/2007. All patients who required open heart surgery were all transferred to Fairview Hospital for open heart surgery. Staff A confirmed 10 patients who received cardiac catheterization at the facility were transferred from the Lakewood Hospital facility to Fairview Hospital for open heart surgery in the previous 12 months.	H 372		
H 383	3701-84-38 (D) Open Heart Surgery - Intensive Care Unit (D) The provider of an open heart surgery service shall ensure that a fully equipped and staffed cardiac surgical intensive care unit that	H 383	Tag H383 **Corrective Action/Policy Changes:** See Response to Tag H361.	2/25/2015

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H 383	Continued From page 8 meets the needs of the cardiac surgery patient is available in the building and accessible by gurney from where the open heart surgery is performed. The number of available intensive care unit beds shall be approximately one-half the number of open heart operations performed per week however, the beds are not required to be dedicated only to cardiac surgery patients. The physical space of the unit shall meet "Joint Commission on Accreditation of Healthcare Organizations" or American osteopathic association recommended standards, which are in effect on the effective date of this rule, for intensive care unit beds. This STANDARD is not met as evidenced by: Based on observations, staff interview and facility documentation review the facility failed to maintain a qualified post cardiac surgical intensive care team on staff. This deficient practice had the potential to negatively effect any patients who may require open heart surgery at the facility. The facility has not performed an open heart surgery at this facility for seven years. Findings include: 1. Review of the health care facility staff documentation revealed the facility failed to staff any adult post cardiac surgery staff. The records further indicated the dedicated and qualified post open heart surgery intensive care cardiac staff for the facility were in fact, all on the sister facility's staff roster. Additionally all the staff's personnel records and training records were maintained at the sister facility (Fairview). 2. Interview with Staff B on 08/04/14 at 11:17 A.M. Staff B verbalized the Cleveland Clinic enterprise had regionalized their hospital based	H 383	Tag H383 (cont'd) **Educational Efforts:** N/A **Monitoring of Compliance:** N/A	

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H 383	Continued From page 9 cardiac procedures. Staff B verbalized that only in an emergency would the facility perform an open heart surgery in the event a patient was too unstable to transfer to Fairview hospital for surgery and after surgery care. Staff B confirmed the two facilities maintained different Health Care Facility identification numbers. Staff B further confirmed the entire post cardiac open heart surgery team members were all on staff at Fairview Hospital and not on the Lakewood Hospital Staff roster. In the event a patient could not be transferred, the Fairview post open heart intensive care unit staff would travel to the facility to provide care for the patient until the patient was stable enough to transfer to Fairview Hospital post cardiac surgery intensive care unit. 3. Tour of the facility's intensive care unit was completed on 08/05/14 at 10:55 AM and revealed the facility had an eleven bed unit. Interview with Staff E revealed the facility employed no post cardiac surgery nurses. In the event a patient was unable to be transferred and open heart surgery performed at the facility then nurses from Fairview Hospital would travel to Lakewood Hospital to provide care for the patient until the patient was stable enough to be transferred to Fairview for the remainder of the post surgical care services.	H 383		
H 402	3701-84-40 (C) Open Heart Surgery - Volume Goals (C) Each open heart surgery service should meet a volume goal of at least two hundred and fifty open heart procedures per year by the	H 402	Tag H402 **Corrective Actions:** See Response to Tag H361	2/25/2015

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H 402	Continued From page 10 second full year of operation to ensure efficiency and a minimum floor of competency. This STANDARD is not met as evidenced by: Based on facility documentation review and staff interview the facility failed to attain the open heart surgery volume goals of 250 cases annually. This deficient practice had the potential to negatively effect any patients who sought open heart surgical procedures at the facility. The facility failed to perform any open heart surgeries in the last seven years on site. Findings include: Review of the facility's documentation revealed the facility had failed to perform any open heart surgical procedures for the past seven years. The last open heart surgical procedure was performed at the facility on 11/07/2007. Staff A verbalized all patients who were diagnosed at the facility's cardiac catheterization laboratory and recommended for open heart surgery were then discharged from the facility and transported to another facility for performance of open heart surgery procedures.	H 402	Tag H402 (Cont'd.) **Educational Efforts:** N/A **Monitoring of Compliance:** N/A	

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H 000	Initial Comments Health Care Services Inspection Administrator: Shannan Ritchie, Interim Director County: Cuyahoga Number of Cardiac Catheterization labs: Two Services: Adult Cardiac Catheterization high risk procedures The following violations were issued as a result of the Health Care Services Inspection completed on 08/06/14.	H 000	Tag H000 Lakewood 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 Ohio Administrative Code rules for Adult Cardiac Catheterization and Open Heart Surgery are met. This written Plan of Correction was prepared in response to a State Form received from the Ohio Department of Health on January 26, 2015.	
H 040	3701-84-08 (A) Sufficient/Qualified Staff (A) Each provider of a HCS shall, based on the services provided and the number of patients served, maintain a sufficient number of qualified staff members and other personnel and an appropriate schedule of staff time to meet the needs of its patients in a timely manner. The provider of the HCS shall be responsible for the care provided by the staff and personnel of the HCS. This STANDARD is not met as evidenced by: Based on staff interview and facility documentation review the facility failed to maintain qualified health care services staff. This	H 040	Tag H040 Corrective Action/Policy Changes: On or before February 25, 2015 the Hospital will execute a Shared Services Agreement to contract all necessary adult cardiac catheterization staff from another Fairview Hospital. Files of all adult cardiac catheterization staff will be located onsite in the Human Resources Department and contain the relevant documentation including, but not limited to: applications, competencies, performance evaluations/discipline, orientation, and licensure information.	2/25/2015

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H 040	Continued From page 1 deficient practice had the potential to negatively effect any patients who sought health care service procedures at this facility. The facility performed 276 adult cardiac catheterization procedures in the previous 12 months. Findings include: 1. Review of the facility's communication dated 12/20/12 to the facility's cardiovascular physicians revealed effective 12/23/12 there would be one regional cath lab team that would support after hour emergencies at both Fairview and Lakewood Hospital, part of the Cleveland Clinic enterprise. 2. Review of the health care facility staff documentation revealed this facility failed to staff any adult cardiac catheterization procedures with their own employees other than two X-Ray technicians. The records indicated the dedicated and qualified cardiac catheterization staff for the facility were in fact, all on the sister facility's (Fairview Hospital) staff roster. Additionally all the staff's personnel records and training records were maintained at the sister facility (Fairview Hospital). 3. Interview with Staff B on 08/04/14 at 11:17 A.M. revealed that the Cleveland Clinic enterprise had regionalized their hospital based cardiac catheterization (c. cath.) laboratories and procedures. Staff B verbalized the cath lab team traveled back and forth between Fairview and Lakewood Hospitals to perform catheterization procedures. Staff B confirmed the two facilities maintained different Health Care Facility inspection numbers. Staff B further confirmed the entire cardiac catheterization team members with the exception of two X-Ray technicians were all	H 040	Tag H040 (cont'd) **Educational Efforts:** On or before February 25, 2015, the Senior Director for Cardiovascular Services and the Human Resource Director will educate the Adult Cardiac Catheterization Nurse Manager at the Hospital on the on-site files and the appropriate documentation to be contained in each file. **Monitoring of Compliance:** The Senior Director for Cardiovascular Services will review the staff roster at the Hospital on a quarterly basis and confirm that files are maintained on all current staff. If any deficiencies are identified, the Senior Director for Cardiovascular Services will address the issue with the Nurse Manager and Human Resource Director. Senior Director for Cardiovascular Services is ultimately responsible for ongoing compliance with this tag.	

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(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) COMPLETE DATE
H 040	Continued From page 2 on staff at Fairview Hospital and not on the Lakewood Hospital staff roster.	H 040		
H 301	3701-84-30 (C) Adult Cardiac Cath - High Risk Patients (C) A provider of cardiac catheterization services may perform cardiac catheterization and electrophysiology procedures on high-risk patients and may perform high-risk and therapeutic percutaneous coronary interventions (PCI), including percutaneous transluminal coronary angioplasty (PTCA), only if: (1) An on-site adult open heart surgery service is available within the same hospital as the cardiac catheterization laboratory and is immediately accessible from the cardiac catheterization laboratory by gurney; and (2) An experienced cardiovascular surgical team is readily available in less than sixty minutes on a twenty-four hour basis in the event that emergency open heart surgery is required. This STANDARD is not met as evidenced by: Based on observation, staff interview and facility documentation review the facility failed to utilize the required on site adult open heart surgical suite. This deficient practice had the potential to negatively effect any patients who might require open heart surgery related to the performance of high risk cardiac catheterization procedures at the facility. The facility performed 276 adult cardiac catheterization procedures in its high risk cardiac catheterization laboratories in the previous 12 months. The facility transferred 10 patients who	H 301	Tag H301 **Corrective Action/Policy Changes:** On January 27, 2015, Hospital Administration and Physician Leadership conducted a review of the open heart surgical programs, coronary interventions and high-risk cardiac catheterization programs. As a result of the review and confirmation that no open heart surgery had taken place at the Hospital since 2007, the Hospital will no longer offer these service lines as of February 25, 2015. The Hospital will continue to provide low-risk cardiac catheterization services and will meet the low-risk standards outlined in OAC 3701-84-30. **Educational Efforts:** The Medical Executive Committee will be informed of this decision at its meeting on February 2, 2015. Members of the Cardiology Section will be informed at the Section meeting which will occur on or before February 25, 2015. Other relevant staff, including Nursing, Emergency Department personnel and EMS services will be informed on or before February 25, 2015. **Monitoring of Compliance:** Medical Director for Cardiovascular Services is ultimately responsible for ongoing compliance with this tag.	2/25/2015

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	OHCS00066	A. BUILDING: _____ B. WING _____	08/06/2014

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H 301	Continued From page 3 required open heart surgery following cardiac catheterization at the facility in the previous 12 months. Findings include: 1. Review of the facility's documentation entitled Fairview and Lakewood Hospitals Scope of Service, Operations, and Standards of Care Protocol - Invasive Cardiology with a last approved date of 08/06/13 directed on page 2 of the seven page document that Selected Criteria for Identifying High Risk Conditions for Cardiac Catheterization: patients with high risk conditions listed below may require emergency catheter-based therapeutic interventions or open heart surgery. Hence, they shall undergo cardiac catheterization only in a catheterization laboratory that has an open heart surgical support available on site (i.e. accessible from the catheterization laboratory by gurney). Tour of the facility's two cardiac catheterization laboratories and two open heart suites completed on 08/04/14 revealed the facility had two fully equipped operating rooms dedicated for open heart surgery and the necessary heart lung bypass machines which were also fully maintained and operational. Review of the facility's documentation entitled Cardiac Catheterization Patients to FV (Fairview Hospital) for Cardiac Surgery documented 10 patients were transferred from Lakewood following cardiac catheterization to the facility's sister hospital at Fairview for open heart surgery. Additionally, the documentation revealed the facility had transferred 34 patients between January 2012 and July 2014.	H 301		

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H 301	Continued From page 4 Interview with Staff A on 08/05/14 at 1:05 P.M. confirmed the facility performed 276 cardiac catheterizations in the past twelve months. Staff A verbalized the facility has not performed an open heart surgery on site since 11/05/2007. Staff A verbalized that under the Cleveland Clinic regionalization plan, all patients who required open heart surgery were transferred to Fairview Hospital for open heart surgery procedures. Staff A confirmed 10 patients who received cardiac catheterization at the facility were discharged from the facility and transported via ambulance to Fairview Hospital within 24 hours for open heart surgery. Staff A verbalized the 24 hour period was usually related to bed availability at Fairview Hospital.	H 301		
H 343	3701-84-34 (D) Adult Cardiac Cath - Volume Goals (D) The provider of a cardiac catheterization service should meet the following volume goals, per year, by the second full year of operation: (1) For each catheterization service - three hundred procedures; (2) For each catheterization service in which percutaneous coronary interventions are performed - at least two hundred of these procedures. This STANDARD is not met as evidenced by: Based on facility documentation review and staff interview the facility failed to attain the annual open cardiac catheterization volume goals of 300 cardiac catheterization procedures and 200	H 343	Tag H343 **Corrective Action/Policy Change:** On January 27, 2015, Hospital Administration and Physician Leadership conducted a review of the cardiac catheterization program. The Hospital will no longer offer coronary interventions or high-risk cardiac catheterization services as of February 25, 2015. However, the Hospital is committed to maintaining a high quality, low-risk adult catheterization lab. The Hospital will support this service line by reinforcing to the medical staff the services available, quality of care, ease of scheduling and supporting services (i.e. stress testing , EKG, echocardiography, event monitoring & vascular ultrasound).	2/25/2015

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H 343	Continued From page 5 percutaneous coronary interventions annually. This deficient practice had the potential to negatively effect any patients who sought cardiac catheterization procedures at the facility. Findings include: Review of the facility's documentation revealed the facility performed 177 cardiac catheterization's and 99 percutaneous coronary intervention procedures in the previous 12 months. Interview with Staff A on 08/05/14 at 12:17 P.M. confirmed the facility had failed to maintain the required volume goals for cardiac catheterization procedures with and without interventions.	H 343	Tag H343 (cont'd.) **Educational Efforts:** On or before February 25, 2015, the Cardiology Section will meet and the Medical Director for Cardiovascular Services will educate the staff on the following items: 1) open heart surgeries, coronary interventions and high-risk cardiac catheterization services will no longer be offered at the Hospital as of February 25, 2015; 2) low-risk adult cardiac catheterizations will remain available; 3) the service line's quality of care, ease of scheduling and supporting services (i.e. stress testing); 4) the medical criteria for appropriateness of low risk catheterizations and 5) the new reappointment criteria for performing catheterizations at the Hospital. **Monitoring of Compliance:** The Medical Director of the Catheterization Lab and the Medical Director for Cardiovascular Services will meet on a quarterly basis to review the service line functionality and address any ongoing concerns with the Cardiac Catheterization service line. The Medical Director of Cardiovascular Services is ultimately responsible for ongoing compliance with this tag.	
H 344	3701-84-34 (G) Adult Cardiac Cath - Retention of Privileges (G) The provider of a cardiac catheterization service shall have explicit criteria indicating the number of times each year an appropriately privileged physician shall perform each catheterization procedure in order to retain privileges to perform that procedure. These criteria shall be consistent with current recommendations of recognized professional societies and accrediting bodies. This STANDARD is not met as evidenced by: Based on review of the facility active physician roster, delineation of privileges documentation, and facility procedure documentation the facility failed to enforce their volume requirement for the continued performance of Percutaneous Tansluminal Coronary Angioplasty (PTCA)	H 344	Tag H344 **Corrective Action/Policy Changes:** Privilege delineation forms will be revised to remove coronary interventions and open heart privileges from any license independent practitioner who currently holds those privileges after the Open Heart Surgery service line ends on February 25, 2015. Additionally, for any physician privileged to perform diagnostic heart catheterizations, the privilege delineation forms will be revised to include criteria indicating the number of times in a reappointment period a physician	02/25/2015

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H 344	Continued From page 6 interventions. This deficient practice had the potential to negatively effect any patient who required a cardiac catheterization intervention at the facility. The facility performed 99 interventions in the preceding 12 months. Findings include: Review of physician credentialing and privileging documentation directed that clinical privileges in cardiology required that PTCA privileges required an annual volume requirement of 50 PTCA procedures to retain PTCA privileges at the facility. Review of the physician credentialing files completed on 08/05/14 revealed the facility granted performance of PTCA privileges to eight physicians who were currently permitted to perform PTCA at the facility, but had failed to maintain the required 50 PTCA annually. Interview with Staff B confirmed on 08/06/14 at 11:31 A.M. that eight physicians were currently on the facility's active interventional cardiology staff and permitted to perform PTCA procedures, but had failed to maintain the volume goal of 50 PTCA to retain interventional privileges at the facility.	H 344	Tag H344 (cont'd) must perform a catheterization procedure in order to retain the privileges. The revised privilege delineation form was approved by the Section Chief for Cardiology on February 2, 2015. The revised form was presented and recommended for approval by the Medical Executive Committee on February 2, 2015 and will be presented to the Governing Body for approval on February 18, 2015. Additionally, a new Medical Director of the Catheterization Lab will be appointed on or before February 25, 2015. The new Medical Director will meet all statutory requirements for the position. **Educational Efforts:** Section Chief for Cardiology will recommend and approve the criteria for reappointment. At the Section meeting on or before February 25, 2015, , the Medical Director for Cardiovascular Services will educate the staff on the following items: 1) open heart surgeries, coronary interventions and high-risk cardiac catheterizations will no longer be offered at the Hospital as of February 25, 2015; 2) low-risk adult cardiac catheterizations will remain available; 3) the service line's quality of care, ease of scheduling and supporting services (i.e. stress testing); 4) the medical criteria for appropriateness of low risk catheterizations and 5) the new reappointment criteria for performing catheterizations at the Hospital. **Monitoring of Compliance:** The Section Chief for Cardiology is responsible for determining compliance with the appropriate privileging and credentialing requirements for all physicians performing catheterizations at the time of reappointment prior to recommendation to the Medical Executive Committee and the Governing Body and is ultimately responsible for ongoing compliance with this tag.	