BARBARA ANN
Karmanos
CANCER INSTITUTE
Wayne State University

March 2, 2017

CMS
Non-Long Term Care Certification & Enforcement Branch
Attention: Michael Potjeau
233 North Michigan Avenue
Suite 600
Chicago, Illinoi 60601

CMS Certification Number (CCN): 23-0297
Karmanos Cancer Center

Dear Mr. Potjeau,

Please find enclosed a response to your letter dated February 22, 2017 which we received on February 28, 2017 via Certified Mail (Article Number 7002 0860 0000 5116 8583) asserting that the Karmanos Cancer Center was in non-compliance with the Medicare Conditions of Participation.

The enclosed details our response to the Summary Statement of Deficiencies and Plan for Correction. Respectfully, Karmanos Cancer Center firmly believes that we are in compliance with the Conditions of Participation. In addition, we have provided clarification on our Infection Control processes. If you have any questions, we welcome the opportunity.

Respectfully,

Justin F. Klamerus, MD, MMM
President
Karmanos Cancer Center

JFK/bbj

cc: Gerold Bepler, MD, PhD, President & CEO, Karmanos Cancer Institute
Mark O'Halla, EVP and Chief Operating Officer, McLaren Health Care

4100 John R
Detroit, Michigan 48201
1-800-KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org

NCI
Designated Comprehensive Cancer Center

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
230297	A. BUILDING B. WING	01/31/2017

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
Karmanos Cancer Center	4100 John R Street Detroit Michigan 48201

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	Facility ID: 830520A The purpose of this survey was for Complaint Investigation MI00084574 and verification of compliance with the Conditions of Participation for Infection Control and Surgical Services. The Department of Licensing & Regulatory Affairs has evaluated this facility and determined it is not in compliance with federal certification requirements on the date indicated above.	A 000	In the following pages, please find Karmanos Cancer Center's corrective actions which provide evidence that we are in compliance with the Medicare Conditions of Participation.	
A 747	482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.	A 747		
	This CONDITION is not met as evidenced by: Based on observation, interview, and document review the facility failed to ensure biohazards were labeled, hand hygiene was performed consistently, and the Infection Control Program surveillance activities included surgical site infections, resulting in the potential for ongoing acquisition of healthcare associated infections and transmission of infectious agents among patients and staff. See specific findings in A-749: failure to provide a sanitary environment and maintain an active program for the prevention, control, and investigation of infections.		Harper Hospital and Karmanos Cancer Center Logistic's staff removed all specimen bags without bio-hazard labeling from unit/department stock and replaced with properly labeled biohazard specimen bags. Biohazard labeled transport container corrective action - see page 2 Hand hygiene corrective action - see page 3 Infection Control Program surveillance corrective action - see pages 4-5	3/1/2017
A 749	482.42(a)(1) INFECTION CONTROL PROGRAM The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.	A 749	See pages 2-5	

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Justin Klamens, MD	President	3/3/2017

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A 749	This STANDARD is not met as evidenced by: Based on observation, interview and document review the facility failed to provide a clean environment and maintain an Infection Control Program that included surveillance activities of surgical site infections resulting in the potential for the spread of infectious disease. Findings include: On 01/30/2017 at 1030 during tour of the fifth floor Intensive Care Units, the dirty utility room #5228 was observed for the "Soiled Medical Equipment/Instrument Pre-Cleaning and Transport Process." The dirty utility room had a shelf next to the hopper (modified toilet for the flushing of waste) that contained an open yellow 2 bin container labeled for "dirty medical equipment." A wrapped pair of hemostats was in one of the two bins. There were no gloves or eye protection available for staff use. The secure red Biohazard bin was not able to be located for the transport of the dirty equipment. Additionally the plastic bags to put the dirty equipment into had to be obtained from the clean supply room across the hall, the bag was not puncture resistant, and it did not have the Biohazard warning on the outside. Staff C the director of Quality stated "Karmanos purchases the secure red bins for the transport of dirty equipment to the central processing area, but the transporter forgets to bring them back." On 1/30/2017 at approximately 1045 tour of the fifth floor Post Operative Intensive Care Unit was conducted. Upon observation of the "Soiled Medical Equipment/Instrument Pre-Cleaning and Transport Process" in the room designated as "Soiled Utility" it was noted that the dirty equipment processing area did not have a hopper for the disposal of waste. "Maxzyme Foam" (an enzymatic cleaner) was available for the cleaning of dirty instruments. A secure red bin for transporting to central processing was not present and there were no plastic biohazard bags. Staff I was asked were the biohazard bags were located for staff to put the dirty equipment into, He stated "let me find out."	A 749	Yellow 2 bin container removed and replaced with appropriate red bin. Hemostat removed and sent to central sterile processing. All in-patient soiled utility rooms were stocked with red, impervious, bio-hazard labeled bins with lids by unit managers. All inpatient soiled utility rooms were stocked with disinfectant wipes for cleaning instruments, personal protective equipment such as gowns, gloves, masks/eye protection, enzyme pre-cleaner, reference binder with policy and procedure for handling soiled surgical equipment. Infection preventionist rounded on all units to confirm correct materials/equipment. A daily check for presence of a red impervious bins implemented. Clinical Managers instructed to call DMC Logistics manager whenever a red impervious bio-hazard transport bin is not replaced in order to obtain a replacement immediately. Infection preventionist educated all Clinical Managers regarding proper transport of soiled surgical instruments from point of service to soiled utility room. Only the red, impervious bio-hazard bin is utilized to transport the instrument, not plastic bags. Infection preventionist updated Policy IC 116 Cleaning and Disinfection and staff competency. Clinical managers in process of educating all unit/department staff on policy IC 116 Cleaning and Disinfection. ANSI AAMI ST58:2013 purchased. Reference for Infection Preventionist. 5ICU without hopper in soiled utility room will only use disinfecting wipes to clean soiled instruments. Room stocked with disinfecting wipes and sign over sink "for hand washing only".	1/30/2017 1/31/17 2/03/17 1/31/2017 1/31/2017 2/16/17 due date 3/17/2017 3/2/17 1/31/2017

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A 749	He returned with a plastic patient belonging bag that was not puncture resistant or labeled as a biohazard. On 01/31/2017 at 1300 observation on the first floor Wentz unit was conducted. Staff 0 was observed cleaning an examination room after a procedure. She was wearing gloves to remove all linen and then do the initial cleaning of the soiled speculum (medical equipment used for the examination.) She placed the speculum in a secure bin labeled with biohazard warning symbols, she then carried the container to the decontamination room without changing her gloves or performing hand hygiene. She place the sealed container on the counter for further processing and returned to the exam room and then changed her gloves without performing hand hygiene. When this was brought to her attention she removed her gloves and performed hand hygiene. The tour continued to the unit's decontamination room at approximately 1320 at which time Staff P was observed completing the cleaning and preparation for equipment to be returned to the central processing area. Staff P completed the cleaning of the speculum and was also cleaning a laryngoscope from a previous procedure. He failed to perform hand hygiene between glove changes between the two pieces of equipment. When queried, he stated "I can't get the new gloves on if my hands are wet." On 01/30/2017 at 1300 the policy titled "Soiled Medical Equipment/Instrument Pre-Cleaning and Transport Process" #IC 116 dated 09/23/2016 on page 1 of 1 "...C...segregate in a puncture resistant container ..K. If container or tray is not of solid construction, place in plastic bag and attach biohazard sticker...N. Remove personal protective equipment (PPE) and perform hand hygiene."	A 749	Infection preventionist and Quality/Regulatory staff member provided hand hygiene tip sheet to all clinical management. Infection preventionist posted additional hand hygiene signage in Wertz clinic and Infusion center. Managers re-educated unit/department staff on proper hand hygiene. Clinical managers have documented each employee's review of hand hygiene protocol. Infection preventionist, Quality/Regulatory staff and administrative supervisors continue using hand hygiene observation tool to monitor compliance with proper hand hygiene. Additional "Secret shopper" observers added. Results of hand hygiene audit reported at Infection Control committee and shared with managers. ICC minutes go to Medical Executive committee. Director of Ambulatory Clinics counseled two employees who did not follow hand hygiene policy as it relates to glove use and prevention of cross contamination. Infection preventionist updated IC 116 Cleaning and Disinfection policy and staff competency. Specific policy changes include: "instruments must be transported in a rigid, sealable, bio-hazard labeled container"; removed from policy "transportation of any instrument or tray in a plastic bag".	2/3/2017 3/1/2017 2/3/2017 and on-going 2/1/2017 1/31/2017 2/16/17

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A 749	On 01/30/2017 at 1500 the Infection Control Committee Minutes were reviewed from 4/1/2016 to present. The minutes dated 6/8/2016 on page 1 of 6 under 2...e. "No Surgical Site Infections (SSI) identified with colon or hysterectomy surgeries during the first quarter." The minutes dated 9/14/2016 on page 2 of 7 under 2...e. "One SSI with a colon surgery and 5 SSI's with other types of surgeries were identified in the second quarter. Harper will no longer be reporting Karmanos Cancer Center (KCC) SSI's to the Centers for Disease Control as they consider KCC patients to be outpatients. Centers for Medicaid/Medicare does not require SSI's from outpatients to be reported."	A 749	KCC leadership held meeting with Harper Leadership to discuss contractual agreement obligations. KCC Infection preventionist, Infection Control chair and regulatory staff held meeting with Harper Hospital Infection Control staff & leadership to develop a mutually agreeable action plan for monitoring SSIs which includes the following actions: Implement Root Cause Analysis (RCA) process for targeted surgical site infections. Karmanos Cancer Center (KCC) Infection preventionist will share RCA with Harper Infection Control department. Harper Hospital will incorporate KCC surgical site infection data for tracking and trending and share findings with KCC. Surgical Site Infections noted in KCC patients that meet criteria for targeted surgical procedures (hysterectomy, colorectal surgeries) will be shared with Harper Hospital. Harper Hospital will provide overall rate for targeted surgeries including KCC patients. KCC Infection preventionist will develop SSI rates for hysterectomy and colorectal cases utilizing denominator data from finance. KCC Infection preventionist and hospital epidemiologist will continue to perform surveillance for all surgical patients and analyze and review all cases. New process: Clinical Improvement Specialist will preform clinical validation review of all SSIs. Data will be shared at Infection Control Committees at both sites. Karmanos Cancer Center and Harper Hospital Infection Control staff will attend each other's site Infection Control committee meetings. Surgical site infections will be presented and reviewed at the Infection Control Committee meetings at both sites. Harper Hospital Infection Control department will provide surgical suite rounding data (cleaning, humidity, temperature) to KCC infection preventionist which will assist in the thorough review of SSIs.	2/9/2017 and on-going 3/1/2017 Implement 3/6/2017 Implement 3/6/2017 3/1/2017 2/1/2017 Implement 3/15/2017 Implement 3/15/2017

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	On 01/31/2017 at 1230 Staff E the Infection Control Officer was interviewed. She reported that she did go to Harper hospital infection committee meetings and reports back to the KCC infection control committee. She was asked if she had done an analysis on the SSI's that had been reported to her in September. She stated "No." She went on to say that she did not realize that she had to take over the surveillance that included infection detection, data collection, analysis, monitoring and evaluation of preventative interventions now that Harper is no longer reporting KCC infections." On 01/31/2017 at 1400 review of the policy titled "Surveillance Methodology" #IC159 dated revised 08/22/2016 revealed on page 1 of 2 "4...Karmanos Infection Control Department will identify hospital associated infections..."	A 749	All surgery types have always been monitored for infection at KCC by the Infection preventionist. These infections have been and will continue to be reported at the KCC Infection Control Committee. The statement regarding "No" response to "analysis of SSIs reported to her in September" is not reflective of the interview conducted. The infection preventionist explained that KCC does not report surgical site infections through NHSN/CDC. KCC has received IPPS measure exception from CMS for several measures including surgical site infections. The statement regarding "she went on to say that she did not realize....now that Harper is no longer reporting KCC infections" is also not reflective of the interview conducted. This discussion was regarding the reporting of KCC surgical site infections to CMS through NHSN that was suspended by Harper because Harper had received clarification from CMS regarding exemption for reporting surgical patients who are not admitted to their hospital post operatively. KCC surgical patient surveillance that includes infection detection, data collection, analysis, monitoring and evaluation of preventative interventions has always been and will continue to be conducted. Surveyors reviewed 1st, 2nd and 3rd Quarter data from 2016 by way of minutes and meeting materials. It was explained to surveyors that 4th Q data was not included due to monitoring criteria time frame (30-90 days post op) and as of January 30, 2017 this was still in process. New process: Post-operative phone call interviews by KCC staff implemented and include a review of patient signs and symptoms of possible post-operative infection. Those that are flagged as possible infection trigger a notification to the Infection Control practitioner for follow up.	3/1/2017

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