IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

DEBRA RANSOM, R.N.,R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, ID 83720-0009
PHONE 208-334-6626
FAX 208-364-1888

October 9, 2014

Cari Taylor, Administrator
Pacific Cataract & Laser Institute - Lewiston
3330 4th Street
Lewiston, ID 83501-4405

RE: Pacific Cataract & Laser Institute - Lewiston, Provider #13C0001043

Dear Ms. Taylor:

This is to advise you of the findings of the Medicare survey of Pacific Cataract & Laser Institute - Lewiston, which was conducted on September 17, 2014.

Enclosed is a Statement of Deficiencies/Plan of Correction Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction. It is important that your Plan of Correction address each deficiency in the following manner:

An acceptable plan of correction (PoC) contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of the Form CMS-2567.

After you have completed your Plan of Correction, return the original to this office by **October 22, 2014,** and keep a copy for your records.

Thank you for the courtesies extended to us during our visit. If you have questions, please call this office at (208) 334-6626.

Sincerely,

GARY GUILES
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

GG/pmt
Enclosures

October 21, 2014

Gary Guiles, RN
Health Facility Surveyor
Non-Long Term Care

Gary,

Enclosed is the Medicare Recertification Survey Plan of Correction for Pacific Cataract & Laser Institute, Lewiston. I spoke with Nancy, at your office, this morning. A pdf version was emailed to you today. If you have questions, please contact me via email. To ensure that I don't miss any correspondence please carbon copy –

Debbie Eldredge, Executive VP, COO Debbie.eldredge@pcli.com
Jenny Bauska, Surgery Coordinator, RN jenny.bauska@pcli.com
Julie Gothard, Accreditation Coordinator Julie.gothard@pcli.com

It was a pleasure to work with you, Trish & Cheri.

Sincerely,

Cari Taylor

Cari Taylor, ASC Manager
Pacific Cataract & Laser Institute
Cari.Taylor@pcli.com

3330 4th Street
Lewiston, ID 83501

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001043	A. BUILDING _____ B. WING _____	09/17/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PACIFIC CATARACT & LASER INSTITUTE - LEWISTON	3330 4TH STREET LEWISTON, ID 83501

(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
Q 000	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgery center conducted from 9/16/14 to 9/17/14. Surveyors conducting the recertification were: Gary Guiles, RN, HFS, Team Leader Cheri Samuels, RN, MS, HFS Trish O'Hara, RN, HFS Acronyms used in this report include: AORN - Association of Perioperative Registered Nurses ASC - Ambulatory Surgery Center CDC - Center for Disease Control H&P - History and Physical Examination RN - Registered Nurse TLC - Tender Loving Care, the Pre and Post Procedure waiting area at the ASC	Q 000		
Q 082	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.	Q 082	RECEIVED OCT 23 2014 FACILITY STANDARDS	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Cari E. Taylor	ASC Manager	10-21-2014

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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Q 082	Continued From page 1 (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interviews and review of policies, personnel files and quality improvement program documents, it was determined the ASC failed to ensure quality indicator and adverse event data were tracked, monitored, and analyzed to improve processes in patient care. This affected the care of 1 of 23 patients (#22)whose records were reviewed. This resulted in the ASC's inability to implement strategies for organizational improvement in patient care and safety or to examine causation and implement improvements related to adverse events. Findings include: 1. The ASC failed to incorporate, monitor, or identify improvement in patient care. The data provided for review were undated documents titled, "Infection Control Survey." Documentation of the ongoing collection and monitoring of data for patient care and patient safety indicators was not available. There were no reports of ongoing infection control data to review over time to determine if performance was improving or declining. On 9/16/14 at 11:15 AM, during an interview with the Site Manager and the ASC Lead RN, both confirmed the ASC could not produce any documentation related to the use of infection control data in its QAPI program. The ASC failed to collect and use data to monitor	Q 082	Due to space constraints, please see attachment titled Q082-1	

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Q 082	Continued From page 2 the effectiveness and safety of its services. This impeded the ability of the ASC to develop and implement strategies to improve patient care. 2. On 9/16/14 at 2:00 PM, during personnel file review, a memorandum dated 1/31/14 was found in a staff file. The memorandum addressed an adverse event that occurred on 1/15/14 with Patient #22. The event was related to a surgical tray that could not be confirmed as sterile. As noted in the memorandum dated 1/31/14, "the strip on the tray was still pink meaning it had not confirmed complete sterilization. The scrub technician continued with the case and did not inform the surgeon." The questionable surgical tray was used for the surgery. The "Operating Room Record," dated 1/15/14 at 1:42 PM, stated Patient #22 received a dose of Vigamox, an antibiotic ophthalmic solution used to treat bacterial infections of the eyes. On 9/16/14 at 3:50 PM, the Site Manager confirmed the incident occurred. She stated there was no notation of this event in the incident reporting system or documentation of any causal analysis. She stated there was no documentation of any action that was taken to prevent a future event. The Site Manager stated the corporate staff investigated the event but she said no documentation of this could be produced. The policy "Adverse Event Program," not dated, stated adverse events would be analyzed to look for systemic causes and improvements in processes. This was not done. On 9/16/14 at 3:50 PM, the Site Manager confirmed the policy was not followed. The ASC failed to implement preventive	Q 082	Due to space constraints, please see attachment titled Q082-2	

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Q 082	Continued From page 3 strategies that targeted adverse patient events and to ensure that all staff were familiar with improvement strategies.	Q 082		
Q 231	416.50(f)(1) PRIVACY The patient has the right to - (1) Personal privacy This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to ensure personal privacy was provided to patients. This directly affected 2 of 2 patients (#21 and #23), whose surgeries were were observed, and had the potential to affect all patients at the ASC. This resulted in the availability of personal patient information and images to unauthorized persons without patients' consent. Findings include: Between 9:00 AM and 10:36 AM on 9/17/14, the pre-operative/post-operative/waiting area of the ASC was observed. The area was 1 large open room which also included bays for medication procurement and preoperative anesthesia, which consisted of regional blocks to anesthetize the eye. The room was full. At least 8 persons, including Patient #21 and other patients and their guests, were observed in the room at 9:15 AM on 9/17/14. Patients wore name tags which included their full names on their shirts. Two television monitors, 1 in the medication area and 1 in the anesthesia area, were visible from the waiting area. These monitors broadcast patient surgeries in real time. Staff were observed to obtain patients' permission for	Q 231	Due to space constraints, please see attachment titled Q231	

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Q 231	Continued From page 4 visitors to watch surgeries from a viewing area but no permission was obtained to broadcast the surgeries on the monitors. The surgeon was observed to talk with patients prior to surgery, interviewing 1 and then the other. No privacy was provided for these interviews, which included items such as medications the patient was taking, health history, and any health problems the patient had experienced since their history and physical examinations were conducted during an earlier visit. The Lead RN, who supervised the room, was interviewed at 10:35 PM on 9/17/14. She confirmed name tags using full patient names were used for all patients. She confirmed a private area was not used to conduct interviews. She stated the surgeries were being broadcast on the monitors in real time. The ASC did not protect patients' personal privacy.	Q 231		
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on a building tour, staff interviews, and observation, it was determined the ASCs infection control and prevention program failed to ensure	Q 242		

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Q 242	Continued From page 5 the surgical services areas adhered to current infection practices related to the storage of clean and dirty supplies. This resulted in the potential for cross contamination and the spread of infection. Findings include: 1. On 9/16/14 beginning at 9:20 AM, a tour of the facility was made with the Site Manager and the Surgical Assistant. Surveyors observed the eye medications Healon 10 mg and Visacoat 0.5 ml, that were used during surgery in the sterile Operating Room, were being stored in a refrigerator in the Dirty Utility Room. The Dirty Utility Room contained biohazard material and garbage. This practice was confirmed with the Site Manager and Surgical Assistant at the time of the tour. The AORN Journal, dated August 2010, Volume 92, Number 2, titled "Clinical Issues, Proper Equipment Storage in Perioperative Services," recommended "preventing cross-contamination from dirty to clean supplies and equipment; that clean supplies and equipment should not be mixed with dirty items in a dirty utility room or workroom." The article stated the failure to prevent cross contamination put patients at risk for infections. The ASC failed to store medications in clean areas to prevent cross contamination.	Q 242	Due to space constraints, please see attachment titled Q242	

Q082-1

1. The ASC failed to incorporate, monitor, or identify improvement in patient care. The data provided for review were undated documents titled, "Infection Control Survey." Documentation of the ongoing collection and monitoring of data for patient care and patient safety indicators was not available. There were no reports of ongoing infection control data to review over time to determine if performance was improving or declining.

On 9/16/14 at 11:15 AM, during an interview with the Site Manager and the ASC Lead RN, both confirmed the ASC could not produce any documentation related to the use of infection control data in its QAPI program.

The ASC failed to collect and use data to monitor the effectiveness and safety of its services. This impeded the ability of the ASC to develop and implement strategies to improve patient care.

WHO is responsible: Cari Taylor, ASC Manager

HOW the deficiency will be corrected: The ASC Manager will monitor & document infection control program data according to the scope of the QAPI program to improve the quality of clinical outcomes & insure patient safety.

WHEN will it be corrected: On or before November 10, 2014

WHAT will be done to ensure future compliance: ASC Manager will hold Quarterly QAPI Committee Meetings and those meetings will be scheduled using Manager's Microsoft Outlook Calendar.

The ASC Manager will coordinate with the Lead RN to ensure that biannual infection control surveys & quarterly Infection control spot checks are dated, documented & accessible to staff & Health Facility Surveyors. Results will be presented at QAPI Committee meetings. Site specific infection control data is collected & recorded in several capacities/programs –Monthly Infection Log; Risk Management Report; Quality Indicator Tracking Log...Quarterly Clean. These logs & reports will become standing items on committee meeting agendas. Committee members will determine if further data collection &/or analysis is required. Meeting minutes will be fleshed-out to include determination/discussion & any handouts (charts, tables, etc.) will be included in the permanent meeting record. If deficiencies are discovered within infection control surveillance; or in an area where guidelines are not being followed 100%; if there is any infection rate above zero - specific site data will be analyzed for improvement or a change in procedure.

Q082-2

2. On 9/16/14 at 2:00 PM, during personnel file review, a memorandum dated 1/31/14 was found in a staff file. The memorandum addressed an adverse event that occurred on 1/15/14 with Patient #22. The event was related to a surgical tray that could not be confirmed as sterile. As noted in the memorandum dated 1/31/14, "the strip on the tray was still pink meaning it had not confirmed complete sterilization. The scrub technician continued with the case and did not inform the surgeon." The questionable surgical tray was used for the surgery. The "Operating Room Record," dated 1/15/14 at 1:42 PM, stated Patient #22 received a dose of Vigamox, an antibiotic ophthalmic solution used to treat bacterial infections of the eyes.

On 9/16/14 at 3:50 PM, the Site Manager confirmed the incident occurred. She stated there was no notation of this event in the incident reporting system or documentation of any causal analysis. She stated there was no documentation of any action that was taken to prevent a future event. The Site Manager stated the corporate staff investigated the event but she said no documentation of this could be produced.

The policy "Adverse Event Program," not dated, stated adverse events would be analyzed to look for systemic causes and improvements in processes. This was not done. On 9/16/14 at 3:50 PM, the Site Manager confirmed the policy was not followed.

The ASC failed to implement preventive strategies that targeted adverse patient events and to ensure that all staff were familiar with improvement strategies.

WHO is responsible: Jenny Bauska, Corporate Surgery Coordinator, Cari Taylor, and ASC Manager

HOW the deficiency will be corrected: Perform accurate/appropriate written documentation on all aspects of Adverse Events.

The incident on 1/31/14 was discussed and analyzed in depth with the staff in question. Corporate was involved and staff members interviewed. Causal analysis confirmed the event was not a systemic or protocol problem–but rather an isolated personal issue caused by staff's neglect to follow protocol.

Staff member received official counseling/re-education followed up by disciplinary actions. Corporate and local Site Manager felt confident that the isolated event was resolved. Management recognizes the importance of documentation of all incidents.

WHEN will it be corrected: On or before November 10, 2014

WHAT has been done/will be done to ensure future compliance: Training/Education.

The Surgery Coordinator & ASC Manager have received training/education on the importance of written documentation covering the investigation of adverse events.

- ASC Manager will receive report of any adverse event within 1 working day or within 1 working day of becoming aware of event.
- ASC manager will immediately begin the process of investigating the details of the event by performing interviews of staff involved
- ASC Manager will gather the details in a written report and that documentation will be posted in the adverse event log

Q231

(1) Personal privacy
This STANDARD is not met as evidenced by:
Based on observation and staff interview, it was determined the ASC failed to ensure personal privacy was provided to patients. This directly affected 2 of 2 patients (#21 and #23), whose surgeries were were observed, and had the potential to affect all patients at the ASC. This resulted in the availability of personal patient information and images to unauthorized persons without patients' consent. Findings include:

Between 9:00 AM and 10:36 AM on 9/17/14, the pre-operative/post-operative/waiting area of the ASC was observed. The area was 1 large open room which also included bays for medication procurement and preoperative anesthesia, which consisted of regional blocks to anesthetize the eye.

The room was full. At least 8 persons, including Patient #21 and other patients and their guests, were observed in the room at 9:15 AM on 9/17/14. Patients wore name tags which included their full names on their shirts.

Two television monitors, 1 in the medication area and 1 in the anesthesia area, were visible from the waiting area. These monitors broadcast patient surgeries in real time. Staff were observed to obtain patients' permission for visitors to watch surgeries from a viewing area but no permission was obtained to broadcast the surgeries on the monitors. The surgeon was observed to talk with patients prior to surgery, interviewing 1 and then the other. No privacy was provided for these interviews, which included items such as medications the patient was taking, health history, and any health problems the patient had experienced since their history and physical examinations were conducted during an earlier visit.

The Lead RN, who supervised the room, was interviewed at 10:35 PM on 9/17/14. She confirmed name tags using full patient names were used for all patients. She confirmed a private area was not used to conduct interviews. She stated the surgeries were being broadcast on the monitors in real time.

The ASC did not protect patients' personal privacy.

WHO is responsible: Jenny Bauska, Corporate Surgery Coordinator, RN

HOW the deficiency will be corrected:

- TV monitors will either be moved to a discrete location &/or Monitor Privacy Screens installed to ensure only staff can view information on the monitors.
- Patient name tags will be changed to first name only. Should two patients have the same first name – the last initial will be used
- Patient Privacy - prior to admission each & every patient receives a copy of our Patient Privacy Notice which describes our policy and practices. Each Patient signs our "Notice of Privacy Practices- Acknowledgement form". If a patient requests extra privacy, a private room will be provided. *no correction necessary.
    - Please see documentation below regarding PCLI's policy for admit process.

Interpretive Guidelines: §416.50(c)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, dressing), during medical/surgical treatments, and when requested as appropriate.

Some background on PCLI: One of our foundational principles is that the typical cataract age group patient is best served with no IV sedation and rare/minimal oral sedation. So we try to provide "sedation of assurance" in various ways. We even

name the pre op area "TLC" (tender loving care) to remind ourselves of the priority. After doing this 300,000 plus times we have learned that most patients are relaxed by feeling like they are part of a group. They encourage one another, learn together as teaching activities take place and see each other walk out of surgery with a smile. This group dynamic is facilitated by living room decor and side by side chairs.

Of course privacy at certain points in the experience is needed by all patients and certain patients prefer privacy to a greater extent than most. Every patient has their pre op exam and counseling in a private exam room. Every patient has their anesthetic injection along with any other private medical history taking and question answering in a private room. But the rest of the time including teaching activities, administration of eye drops and waiting for drops to work they are in a group setting unless they prefer to be in a private setting for those phases.

Excerpts from our "Notice of Privacy Practices" document

Notice of Privacy Practices

CATARACT AND LASER INSTITUTE

This notice describes how medical information about you may be used and disclosed, and how you can get access to this information. PLEASE REVIEW IT CAREFULLY.

Pacific Cataract and Laser Institute (PCLI) maintains a record of the health care services we provide to you. This includes your symptoms, our findings, test results, diagnoses and treatment, health information from other providers, and billing and payment information relating to these services. Federal and state laws allow us to use this information to provide care for you but require us to protect the privacy of this information.

PCLI respects your privacy. We understand that your personal health information is very sensitive. We will not disclose your information to others unless you tell us to do so, or unless the law authorizes or requires us to do so. We are required by law to provide to you this notice of our privacy practices.

How your Health Information is Used

For treatment:

- Information will be used to help decide what care may be right for you.
- This information may be shared with other health care providers caring for you.
- Every patient has their pre op exam counseling, their anesthetic injection, along with any other private medical history taking in a private room. But the rest of the time including teaching activities, administration of eye drops and waiting for eye drops to take effect, patients are in a group setting, unless you prefer to be in a private setting for those phases. Please advise us if you prefer a private setting, and we will accommodate you.

WHEN will it be corrected: On or before November 10, 2014

WHAT will be done to ensure future compliance:

- Re-locating monitors and/or installing monitor privacy screens will permanently ensure compliance that information on the screens is not viewable by anyone other than immediate PCLI Staff.
- Updating the EHR Patient name tag template will permanently ensure compliance that only the patient's first name (and last initial should two patients have the same name) will appear on the nametag.
- Patient Privacy - prior to admission each & every patient receives a copy of our Patient Privacy Notice; each Patient signs our "Notice of Privacy Practices- Acknowledgement form"; if a patient requests extra privacy, a private room will be provided. *no correction necessary.

Q242

1. On 9/16/14 beginning at 9:20 AM, a tour of the facility was made with the Site Manager and the Surgical Assistant. Surveyors observed the eye medications Healon 10 mg and Visacoat 0.5 ml, that were used during surgery in the sterile Operating Room, were being stored in a refrigerator in the Dirty Utility Room. The Dirty Utility Room contained biohazard material and garbage. This practice was confirmed with the Site Manager and Surgical Assistant at the time of the tour.

The AORN Journal, dated August 2010, Volume 92, Number 2, titled "Clinical Issues, Proper Equipment Storage in Perioperative Services," recommended "preventing cross-contamination from dirty to clean supplies and equipment; that clean supplies and equipment should not be mixed with dirty items in a dirty utility room or workroom." The article stated the failure to prevent cross contamination put patients at risk for infections.

The ASC failed to store medications in clean areas to prevent cross contamination.

WHO is responsible: Jenny Bauska, Corporate Surgery Coordinator, RN

HOW the deficiency will be corrected: New refrigerator has been ordered and will be located outside the dirty room

WHEN it was corrected: October 14, 2014 (please see photo of new refrigerator)

WHAT will be done to ensure future compliance: Purchase and placement of the new refrigerator(October 14, 2014) and yearly competency checks will ensure refrigerator remains outside the dirty room.