STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	38C0001000	A. BUILDING _____ B. WING _____	05/22/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LOVEJOY SURGICENTER, INC	933 NW 25TH AVENUE PORTLAND, OR 97210

(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 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: - Based on observations, it was determined that the ASC failed to design, implement, monitor, and evaluate a method to ensure that medications were prepared, labeled, and discarded according to acceptable standards of practice. Findings include: (1) Observation of Patient #22 from admission through discharge on 05/20/15 from 7:15 AM to 11:30 AM, revealed errors in standards of practice for medication labeling and discarding of expired medications. These errors include but were not limited to the following: (a) At 9:45 AM in OR #2, inspection of the medication cabinets in the back of the room revealed 2 opened vials of oxytocin (hormone). Neither vial was labeled indicating when they had been opened or who had opened them or when they would expire. CDC website information for "Injection Safety > Information for Providers > FAQs regarding Safe Practices for Medical Injections" on 07/02/15 revealed: " (Question) When should multi-dose vials be discarded?" "(Answer) Medication vials should always be	Q 181		

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Q 181	Continued From page 4 discarded whenever sterility is compromised or questionable. In addition, the United States Pharmacopoeia (USP) General Chapter 797 [16 <http://www.cdc.gov/injectionsafety/providers/references.html>] recommends the following for multi-dose vials of sterile pharmaceuticals: - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. - If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer ' s expiration date. The manufacturer ' s expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer ' s original expiration date." (b) At 10:40 AM in PAR , inspection of the medication cabinets in the back of the room revealed the following expired medications: - 2 opened vials of oxytocin (hormone). Neither vial was labeled indicating when they had been opened or who had opened them or when they would expire. - 4 IV bags of sterile water - 2 expired 12/14, 2 expired 07/12 - 1 500 ml IV bag of saline expired 11/14 - 12 10 ml vials of saline - expired 09/14 - Gentamicin (antibiotic) - multidose vial expired 12/14 - Naloxone (opiod antagonist, antidote) - single dose vial expired 8/14	Q 181		

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Q 181	Continued From page 5 - Diphenhydramine (antihistamine) - single dose vial expired 4/15 (c) At 11:30 AM, observation of the anesthesia cart revealed the following: - A pre-filled syringe containing a white liquid. This syringe was not labeled indicating what the content were, who had drawn up the substance, the time it had been prepared, or who had prepared it, or when the contents would expire. - CRNA 1 stated "An MA checks for [expiration] dates and if it is outdated it gets thrown out. But we don't throw it out unless there is a replacement" - However further observation revealed a multidose vial of Flumazenil (GABA receptor antagonist, bensodiazepine antidote) was marked opened on 11/01/14, and the vial's printed expiration date was 3/2015. There was another unopened multi-dose vial of Flumazenil, with expiration date of 3/2016, available in the cart. The ASC failed to assure that medications were properly prepared (labeled) and discarded when expired.	Q 181		
Q 221	416.50(a) NOTICE OF RIGHTS An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State	Q 221		

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Q 221	Continued From page 6 agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. This STANDARD is not met as evidenced by: - Based on documentation review, it was determined that the facility's notice of patient's rights given to the patient and the posted notice of patient's rights did not have the correct name of the SA to which patients may report complaints or concerns, or the correct web site information for the Medicare Beneficiary Ombudsman, as required by rule. Findings include: (1) Documentation Review: On 05/19/15 review of documentation in the Lovejoy Surgicenter Notice of Patient Rights, updated 1/15/15, revealed the following: (a) "file a complaint with the State Department of Health Services regardless of whether you use the grievance process. You can contact the State Department of Health Services at: Oregon Department of Healthcare Licensure and Certification" The name of the SA was incorrect. (b) Documentation also listed contact information for the Office of the Medicare Beneficiary Ombudsman which included the website http://www.medicare.gov/Ombudsman/resources.asp. The website information for the CMS Ombudsman was incorrect.	Q 221		
Q 231	- 416.50(f)(1) PRIVACY	Q 231		

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Q 231	Continued From page 7 The patient has the right to - (1) Personal privacy This STANDARD is not met as evidenced by: - Based on observation and interview, it was determined that the ASC failed to provide privacy for patients in pre-op and post-op areas, as required by rule. Findings include: (1) On 05/20/15 at 9:10 AM two patients (#22 & #23) occupied adjoining pre-op bays with the curtain between each bay pulled only 1/3 of the length of the gurney. Observation revealed that the doctor and the CRNA came in to discuss the upcoming procedure with Patient #22. Patient #23 was crying in the next bay over. At 9:15 AM the pre-op medical assistant (MA 1) stated during an interview that the curtains were not extended completely around the gurneys so that staff could view each patient. Observation revealed that it was possible to view each patient if the curtains were extended the full length between the gurneys. By not extending the curtain the entire length of the gurneys, the ASC failed to provide privacy for these two patients. (2) On 05/20/15 at 11:00 AM the same two patients (#22 & #23) were in adjoining post-op (PAR) bays. These bays face out into the semi-restricted hallway. The curtains were fully extended between the gurneys, but open to view from the hall. Patient #22 was discussing birth	Q 231		

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Q 231	Continued From page 8 control methods with RN 2, while Patient #23 was recovering from anesthesia and was observed to be crying. By not pulling the curtains the entire length of the beds, and blocking view from the hallway, the ASC failed to provide privacy for these two patients.	Q 231		
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, interview and professional guidelines, it was determined that the ASC failed to ensure that a sanitary environment was maintained per professional standards of practice in the following areas: (1) Injection practices, (2) Hand hygiene, and (3) Pre-clean of sterilized instruments. Findings include: (1) Injection practices: Observation of Patient #22 from admission through discharge on 05/20/15 from 7:15 AM to 11:30 AM, revealed the following: (a) At 9:15 AM, CRNA 1 placed a peripheral IV catheter into Patient #22's left arm. He/she attached the IV tubing from a previously prepared	Q 241		

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Q 241	Continued From page 9 Lactated Ringers 1 liter bag to the peripheral IV and started the infusion into the patient #22. He/she then inserted a pre-drawn medication syringe into a port of the IV tubing without using an antiseptic swab to clean the port, as recommended by professional standards of practice. The online APIC position paper on "Safe injection, infusion, and medication vial practices in health care" released in April 2010 highly recommends to "Disinfect IV ports and vial stoppers by wiping and using friction with a sterile 70 isopropyl alcohol, ethyl/ethanol alcohol, iodophor, or other approved anti-septic swab. Allow the port to dry before accessing." This standard of practice, should have been performed even when the IV tubing was new out of the package, or the medication vial was newly opened. (b) At 9:25 AM,Patient #22 was moved into OR #2. Observation revealed CRNA 1 draw up medication into a syringe and again insert the medication into the port of the IV tubing without using an antiseptic swab to clean the port, as described by professional standards of practice. (c) At 11:30 AM, observation of the anesthesia cart in OR #2 revealed a multi-dose vial of Lidocaine (local anesthetic) was found to have a multiple-access port (also know as a medication vial adapter) inserted into the rubber septum. This was a break in sterile procedure, as described by professional standards of practice. CDC website "Injection Safety > Information for Providers > FAQs regarding Safe Practices for Medical Injections" on 07/02/15 revealed: " (Question) Is it acceptable to leave a needle or	Q 241		

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Q 241	Continued From page 10 other device inserted in the septum of a medication vial for multiple medication draws? (Answer) No. A needle or other device should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid." (2) Inadequate hand hygiene:Observation of Patient #22 from admission through discharge on 05/20/15 from 7:15 AM to 11:30 AM, revealed the following: CRNA 1 was observed in pre-op and assessing Patient #22. He/she checked the patient's vital signs, asked questions, and documented in the patient's chart. He/she put on gloves to insert the peripheral IV catheter. Once he/she completed inserting the IV and medication administration, he/she took off the gloves, discarded them into the trash, and left the room. Observation failed to reflect that CRNA 1 performed adequate hand hygiene at any time during his/her care of Patient #22. This failure resulted in 4 breaks in the recommended protocol for hand hygiene; specifically 1) coming into room; 2) working with patient and equipment; 3) putting on gloves, or ; 4) taking off gloves. The online CDC/HICPAC "Guideline for Hand Hygiene in Health-Care Settings" released on 10/25/02 and reviewed on 07/02/15 recommends the following: "B. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items. Alternatively, wash hands with an antimicrobial soap and water in all	Q 241		

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Q 241	Continued From page 11 clinical situations described in items C. Decontaminate hands before having direct contact with patients E. Decontaminate hands before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure F. Decontaminate hands after contact with a patient's intact skin (e.g., when taking a pulse or blood pressure, and lifting a patient) I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient J. Decontaminate hands after removing gloves" (3) On 05/21/15 at 2:00 PM, the ST 1 described how pre-cleaning was done for instruments prior to sterilization. When asked how the enzymatic detergent was measured out, along with the water for dilution, the Scrub Tech stated that he/she pumped the bottle an exact number of times, but that the water was filled in the sink to an unmeasured amount. The Medline Instrument Care and Handling brochure found on the Medline company website on 07/02/15 included the directions for use of the "Medline Single or Dual Enzymatic Detergent." The directions for pre-soaking or manual washing of "delicate instruments and scopes" revealed the technician should mix "1oz. of detergent to 1 gallon of water." If the water was not measured, it was not possible to verify whether the concentration of the detergent was correct and failed to follow the manufacturers direction. The ASC failed to ensure that the pre-clean solution was mixed according to manufacturers directions and standards of practice.	Q 241		

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Health Care Regulation and Quality Improvement

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	07-0978	A. BUILDING: _____ B. WING _____	05/22/2015

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B 000	Initial Comments On 05/19/15 through 05/22/15 an unannounced State relicensure survey was completed for Lovejoy Surgicenter in Portland, Oregon to determine compliance with the Oregon Administrative Rules Chapter 333, Division 076, for Ambulatory Surgical Centers. The findings of this survey are reflected in the deficiencies cited in the following pages. Definitions & Abbreviations: ASC: Ambulatory Surgery Center CDC: Centers for Disease Control CRNA: Certified Registered Nurse Anesthetist DO: Doctor of Osteopathy, i.e. physician EHR: Electronic Health Record H&P: History and Physical examination HICPAC: Healthcare Infection Control Practices Advisory Committee IV: Intra Venous MA: Medical Assistant MD: Doctor of Medicine, i.e. physician ml: milliliter OHA: Oregon Health Authority OR: Operating Room P/Ps: Policies and Procedures PAR: Post Anesthesia Recovery (room) post-op: Post-operative pre-op: Pre-operative RN: Registered Nurse SOD: Statement of Deficiencies ST: Surgical Technician	B 000	PLAN OF CORRECTION ACCEPTED Meg L Gribble RN 7/31/15 SIGNATURE DATE	

STATE OF OREGON
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Joy Staples, Administrator 7-30-15

Health Care Regulation and Quality Improvement

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B 070	OAR 333-076-0135(1) Nursing Services: RN (1) An RN shall be responsible for the nursing care provided to the patients. This Rule is not met as evidenced by: - Based on interview and review of documentation, it was determined that the ASC did not have an RN in charge of and responsible for nursing care as required by this rule. Findings include: (1) During the tour of the ASC on 05/19/15 at 9:00 AM, the ASC Administrator explained the current staffing of the nursing services. Several experienced nurses and the previous Nursing Supervisor recently left the ASC and the governing body felt that the current RN's did not have enough experience to supervise the nursing staff and be responsible for patient care. The current supervisor was a long-time employee of the ASC, but was a Surgical Technician and not a Registered Nurse. (2) Review of the "Management and Oversight Information" form, filled out by the ASC Administrator on 05/19/15, revealed that the designated manager of the Nursing Services was ST 1, a Certified Surgical Technician. The ASC failed to have a Registered Nurse responsible for Nursing Services and patient care staff as required. -	B 070		

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B 123	Continued From page 2	B 123		
B 123	OAR 333-076-0160(4) Care of Patients: Discharge Evaluations (4) At the time of discharge from the ASC, each patient must be evaluated by a physician, or by an anesthetist as defined by 45 CFR 410.69(b) for proper anesthesia recovery. This Rule is not met as evidenced by: - Based on observation, policy review, and review of patient medical records it was determined that in 22 of 22 records the ASC failed to have the patient evaluated by either a physician or CRNA for anesthesia recovery following the procedure and prior to discharge, as required by rule. Findings include: (1) Policy Review: On 05/20/15 at 12:40, during review of the ASC Surgical Services policy "Subject: Anesthesia" updated on 5/2011 and reviewed by the Medical Director on 08/20/11 it was revealed that the ASC did not require a discharge evaluation by the MD or a CRNA for patients following surgery. The ASC's policy stated that : "1. All patients will be examined just prior to anesthesia." "2. Evaluation will be completed by an independent Certified Registered Nurse Anesthetist and charted." "3. Documentation of this evaluation will be written on chart, both pre and post operatively." The rule requires an evaluation of the patient by a physician or anesthetist prior to discharge to ensure patient safety and recovery from the procedure. This policy indicated that the pre-op	B 123		

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B 123	Continued From page 3 evaluation would be used for both the pre and post operative documentation, which fails to meet the state requirement. (2) Observation of Patient #22 from admission through discharge on 05/20/15 from 7:15 AM to 11:30 AM, the MD and the CRNA were observed in pre-op evaluating the patient. Observation failed to reflect that the MD or the CRNA evaluated Patient #22 after being placed in post-op (PAR) or prior to discharge. The PAR RN completed the discharge assessment and discharged the patient from the ASC without a final physician or CRNA evaluation. The ASC failed to ensure that an MD or CRNA conducted a final evaluation of the patient prior to discharge. (3) Patient Medical Records were reviewed beginning on 05/19/15 at 2:15 PM, and ending 05/22/15 at 11:30 AM. Documentation revealed 17 of 22 patient records lacked evidence that a post-anesthesia evaluation had been completed by a physician or CRNA (Patients #1,2,4, 6 -10, 14, 15, 17 - 20, 22). The ASC failed to have a physician or a CRNA evaluate patients for post-anesthesia recovery prior to discharge as required.	B 123		
B 126	OAR 333-076-0160(7) Care of Patients: Policy Evaluation (7) Patient care policies shall be evaluated annually and rewritten as needed. Documentation of the evaluation is required. This Rule is not met as evidenced by: - Based on interview and review of the policy and procedure manuals it was determined that the	B 126		

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B 126	Continued From page 4 ASC failed to design, implement, monitor and evaluate a method to ensure that an annual review of the ASC's patient care policy's and procedures had occurred and was documented. Findings include: (1) On 05/20/15 at 12:20 during review of Policy and Procedure manuals the following policies were revealed to not have been reviewed within the last year: (a) "SURGICAL SERVICES, SUBJECT: ANESTHESIA updated 5/2011" was last reviewed on 08/20/11. (b) "SURGICAL SERVICES, SUBJECT: ADMINISTRATION OF ANESTHESIA updated 8/5/08" was last reviewed on 11/22/13. (c) "SURGICAL SERVICES - INFECTION CONTROL, SUBJECT: HAND WASHING AND GLOVE USE. updated 1/12/2010" was last reviewed on 11/22/13. The ASC failed to assure that their policy's and procedure's were evaluated annually and revised as needed. (2) On 05/20/15 at 3:30 PM in interview with the ASC Administrator he/she admitted that the ASC patient care policies had not been reviewed annually. -	B 126		

Health Care Regulation and Quality Improvement

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	07-0978	A. BUILDING: _____ B. WING _____	05/22/2015

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B 139	Continued From page 5	B 139		
B 139	OAR 333-076-0165(2)(h) Medical Records: Dates, Times, Authenticated (2) A legible reproducible medical record shall include at least the following (if applicable): (h) All entries in patient's medical record must be dated, timed, and authenticated: This Rule is not met as evidenced by: Based on documentation review, it was determined that the ASC failed to ensure all entries in the medical record were "dated, timed, and authenticated" for 22 of 22 medical records reviewed. (Records of patients #1 through 22), as required by rule. Findings include: (1) The ASC used the Azalea Electronic Health Record software to document and store patient medical records. Review of patient records beginning on 05/19/15 at 2:15 PM revealed several fields in the Azalea EHR forms that had names of staff providing care and times when the records were signed, but failed to provide the dates when the entries were made. Reviewing the EHR record of Patient #22 on 05/22/15 at 11:30 AM, the following sections were incomplete: (a) "Counseling Notes" was signed by SW 1 at 7:53 AM, but no date was noted. (b) "History" was signed by MD 3 at 9:40 AM, but no date was noted. (c) "Pre-op" was signed by MA 1 at 8:13 AM and	B 139		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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B 139	Continued From page 6 RN 1 at 8:44 AM, but no date was noted for either signature and time. (d) "OR Record" was signed by RN 2 at 9:11 AM, but no date was noted. (e) "Nursing Progress Notes" was signed by RN 1 at 10:47 AM, but no date was noted. (f) "Post Anesthesia Discharge Scoring System" was signed by RN 1 at 11:32 AM, but no date was noted. (g) "Operative Report" was signed by MD 3 at 9:41 AM, but no date was noted. (h) "Safety Checklist" was signed by MA 1, CRNA 1, RN 1, and RN 2 with times for each, but no dates were noted. (i)"Ultrasound" blocks were signed by MD 3 at 9:41 AM, but no dates were noted. (j) "Plan" blocks were signed by MA 1, RN 1, and RN 2 with times for each, but no dates were noted. (2) Printed forms that were signed by both the patient and staff prior to the procedure, were missing a space for "time" to be noted along with a signature and date. The following forms failed to include "time" when patient and staff sign: (a) Consent for Anesthesia Services (b) General Anesthesia Preoperative Questionnaire (c) Laminaria insertion consent form (d) Post-Op Instructions (e) Research Subject Information Sheet	B 139		

Health Care Regulation and Quality Improvement

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B 139	Continued From page 7 The ASC failed to ensure that all the patient's medical records were dated and timed.	B 139		