

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001067		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 02/16/2012	
NAME OF PROVIDER OR SUPPLIER OSMC OUTPATIENT SURGERY CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 2310 CALIFORNIA ROAD, SUITE B ELKHART, IN 46514			
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 009555</p> <p>Survey Date: 2/14/2012 through 2/16/2012</p> <p>Surveyors: Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>Albert Daeger Medical Surveyor</p> <p>QA: claughlin 02/22/12</p>	S0000					

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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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S0153	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on document review and interview, the facility failed to ensure the employees of the contracted housekeeping service received initial job-specific orientation and competency for 3 of 3 staff members (#A11, A12, and A14) and failed to ensure the one PRN nurse (#P4) received job specific orientation.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Documentation in the binder for the contracted housekeeping company indicated some generic training from the company itself for employees #A11, A12, and A14, but no facility specific training. 2. Review of the employee information in the binder failed to indicate any documentation of initial orientation or specific job competencies for any of the 3 housekeeping employees, #A11, A12, and A14. 	S0153	<p>Immediately following the surveyor's departure, the CEO, ASC Director, and Maintance Coordinator met to review the housekeeping items provided during our exit interview. On February 17, 2012 a meeting was held with the contracted housekeeping Manager where by all of the items that were non compliant were addressed. A new contract is currently under development with the daily, weekly, and monthly tasks to be accomplished by the housekeeping staff to include: initial orientation, facility specific training, specific job competencies, proper mixing of chemicals, and Infection Control training. In addition, specific training parameters will be established within the contract and the ASC Director will ensure compliance on a quarterly basis. This will however, occur more frequently during the next quarter to ensure tht the expected behavior is achieved</p>	03/12/2012	

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	<p>3. The binder lacked any documentation of any specific process or order for cleaning or specific chemicals to be used or how the chemicals should be prepared.</p> <p>4. At 5:50 PM on 02/15/12, the contracted housekeeping staff member #A12, indicated he/she had worked at the facility for almost 7 years and received training at the company upon hire, then was shown by another employee how to do the job in the facility. He/she indicated there was no training by the facility nor any written instructions regarding the cleaning process or mixing chemicals. He/she indicated the only time additional training was given was if there was a new process or product to be used.</p> <p>5. At 6:10 PM on 02/15/12, staff member #A1 confirmed the facility did not provide training to the contracted housekeeping staff and did not include them in any annual training related to infection control.</p> <p>6. Review of employee files indicated an incomplete orientation packet for the one PRN nurse, staff member #P4, who was hired 09/07/11. The file contained a job description for a Staff Nurse Pre/Post-Op.</p> <p>7. At 11:15 AM on 02/15/12, staff</p>		<p>immediately. On March 12, 2012 the ASC Director and the OR Lead will be training the housekeeping staff on specific facility cleaning duties as well as Infection Control and Bloodborne Pathogen training. Finally, the housekeeping services contract will be presented to the Board of Directors of the Surgery Center for their approval on March 19, 2012 at their regularly scheduled meeting. Our action plan included a start date of Febraury 17, 2012 followed by two additional meetings between the ASC Director and contracted housekeeping manager on March 5th and March 8, 2012 to discuss the details of the facility specific cleaning and items that were to be included in the housekeeping contract going forward. Our action plan included immediate attention to our housekeeping deficiencies through meetings and actual training of the housekeeping staff by March 12, 2012. However the approval of the housekeeping contract will occur in our 31- 60 day plan since the contract will be presented to the Board for their appoval on March 19, 2012 at their normally scheduled meeting. Going forward, the ASC Director along with the Human Resources Coordinator will ensure that all new employee's (specifically pre-post nursing staff) orientation checklists will be completed, dated, and filed in the</p>		

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	member #A1 indicated the PRN nurse, staff member #P4, did not work very much and was only used for the pain procedures, but confirmed the job description did not limit what the nurse could do.		employment file for each employee. In addition, the completion of the orientation checklist will ensure that all requirements of the pre-post staff (as defined through their job description) are met in order to be employed within the outpatient surgery center. Staff member P4 will be completing her ACLS training prior to resuming any PRN shift work at the outpatient surgery center. Going forward, the ASC Director, in coordination with the Human Resources Coordinator, will ensure that all staff member's orientation checklists are complete and that competencies specific to job description requirements and tasks are achieved.	

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S0156	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (E)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.</p> <p>Based on review of personnel files and interview, the facility failed to ensure all registered nurses (RNs) had current job descriptions for 4 of 7 RN files reviewed (#P5, P6, P9, and P10).</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Review of the employee files for three operating room RNs failed to indicate job descriptions for two of the nurses (#P5 and P6). 2. Review of the employee files for three Pre/Post Op RNs failed to indicate job descriptions for two of the nurses (#P9 and P10). 	S0156	<p>All nursing employment files identified in this tag have been updated and completed with the current job description and signatures by the staff members in compliance with the requirements of the State. In addition, the ASC Director, with the assistance of the Human Resources Coordinator, will ensure that all new employee job descriptions are contained in the employment files with the appropriate signatures from the staff.</p>	02/27/2012	

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	3. At 4:00 PM on 02/14/12, staff member #A1 confirmed the lack of job descriptions in the employee files.				

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S0166	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based on policy and procedure review and interview, the facility failed to ensure there were written, updated, approved policies and procedures for the out-of-lab testing conducted at the center.</p> <p>Findings included:</p> <p>1. Review of the Policy and Procedure manual provided on 02/14/12 by staff member #A1 failed to indicate any policy or procedure for the INR out-of-lab testing performed by staff in the facility.</p> <p>2. The facility policy titled "Pregnant Patients Requiring Elective Procedures", last approved November 15, 2010, indicated, "...5)...If the patient's pregnancy status is unknown, she will be offered the urine pregnancy test in the ASC." The policy did not provide any further information regarding the testing or a procedure to follow.</p>	S0166	<p>Policies for "out of lab testing" to include INR testing, blood glucose testing, and urine pregnancy testing have been developed for the staff for their education. The licensed professional staff completed the "out of lab testing" competencies for INR testing, blood glucose testing, and urine pregnancy testing on Monday, March 5, 2012. In addition, these policies will be presented to the Board for their approval at their regularly scheduled meeting on March 19, 2012. Going forward, these policies and annual competencies will be part of the Policy and Procedure Manual of OSMC's Outpatient Surgery Center. Future compliance will be ensured by the ASC Director during annual staff training.</p>	03/05/2012			

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	<p>3. The facility policy titled "Blood Glucose Level Testing", last approved November 15, 2010, indicated, "...A. Performing a Blood Test 1. Follow the instructions outlined in the manufacturer's users manual. ...B. Quality Control Testing 1. Quality control testing of the glucometer is to be performed daily when in use, according to the manufacturers recommendation and recorded in a glucometer testing log book."</p> <p>4. At 11:10 AM on 02/16/12, staff member #A1 confirmed the lack of policies and procedures for the INR and urine pregnancy testing. He/she indicated the facility used the Rapid Response urine testing and followed the manufacturer's instructions. He/she also indicated the "Blood Glucose Level Testing" policy was based on a glucometer that had since been replaced in the facility.</p>			

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S0432	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(iii) Cleaning, disinfection, and sterilization.</p> <p>Based on observation, manufacturer's literature, and interview, the infection control program failed to ensure chemicals were used appropriately by the contracted housekeeping staff.</p> <p>Findings included:</p> <ol style="list-style-type: none"> At 5:50 PM on 02/15/12, staff member #A12 was observed mixing the cleaning solutions for mopping and cleaning the horizontal surfaces and equipment. The mop water was mixed with 2 ounces of Sanimaster 6 sanitizer with 2 gallons of water. The spray bottle for cleaning was mixed with 1 ounce of disinfectant with 24 ounces of water. The manufacturer's literature for the Sanimaster 6 sanitizer indicated a mixture of 1 ounce per gallon dilution and a 10 	S0432	<p>Consistent with our response to Tag S153, the referenced observations will be addressed in the new contract with housekeeping services with specific identification of tasks to be provided on a daily, weekly, and monthly basis, as well as the training associated with accomplishing those tasks. In addition, the contract will address a delineation of tasks and responsibilities for contracted housekeeping service employees versus the surgery center staff. Specific facility training and training for the proper mixing and use of chemicals is scheduled for Monday, March 12, 2012 in order to ensure that chemicals are being used appropriately by the contracted housekeeping staff. Finally the list of chemicals used by housekeeping was presented to the Infection Control Committee</p>	03/12/2012			

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	<p>minute contact time to be effective.</p> <p>3. At 5:50 PM on 02/15/12, staff member #A12 indicated he/she was originally trained to mix the solutions when he/she was oriented, but did not think it was written anywhere. He/she indicated the disinfectant was sprayed on a rag then the surface areas were wiped and the rag was turned over and used to wipe the surface. He/she indicated the spraying and wiping were done one right after the other.</p> <p>He/she indicated the OR scrub sinks were sprayed with the disinfectant solution, rinsed with water, and dried, otherwise there were streaks left. He/she also indicated the facility's staff did the terminal cleaning of the operating rooms and he/she only cleaned those rooms on Thursdays.</p> <p>4. At 10:30 AM on 02/16/12, staff member #A1 confirmed the facility's staff did the terminal cleaning of the operating rooms. He/she also confirmed the infection control committee did not have an approved list of chemicals used by the housekeeping staff and directions for their use. He/she had just been made aware of a skin problem with several staff members that was traced to the housekeeping staff's improper diluting of chemicals.</p>		for their approval on March 1, 2012.	

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S0526	<p>410 IAC 15-2.5-2 LABORATORY SERVICES 410 IAC 15-2.5-2 (h)</p> <p>(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.</p> <p>Based on review of employee files, facility document review, and interview, the facility failed to ensure 7 of 7 nurses (#P4- 10), who performed out-of-lab testing on patients of the center, had annual competency for the testing.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Review of the training records for nurses #P4- 10 failed to indicated any training since hire date or any annual competency for performing out-of-lab testing. 2. Review of the most recent annual mandatory training, conducted September 28, 2011, failed to indicated any competencies for the out-of-lab testing performed at the center. 3. At 11:10 AM on 02/16/12, staff member #A1 indicated urine pregnancy testing, INR, and blood sugar testing using a glucometer were performed by nurses on patients of the center. He/she 	S0526	Please reference our comments in Tag S166. The ASC Director has written policies for "out of lab testing" to include training upon hire and annual competency training. The ASC Director, along with the assistance from the Human Resource Coordinator, will ensure that these tasks are accomplished going forward. The licensed professional staff completed the "out of lab" competencies on March 5, 2012.	03/05/2012			

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	indicated staff were trained upon hire, but no annual competencies were required or demonstrated.			

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete.</p> <p>Based on medical record review, policy review, and interview, the facility failed to ensure all entries in the patients' medical records were complete in 11 of 25 records reviewed (#N3, N6, N7, N8, N15, N16, N20, N21, N22, N23, and N25).</p> <p>Findings included:</p> <ol style="list-style-type: none"> The medical record for patient #N3, admitted 12/12/11, indicated discharge orders signed by a physician and a nurse, but both entries lacked dates and times. The medical record for patient #N6, admitted 07/05/11, lacked a date or time for the physician's signature on the Anesthesia Evaluation. The medical record for patient #N7, admitted 07/20/11, indicated dates and times, but lacked nurses' signatures on the RN Notes. The medical record for patient #N8, 	S0640	<p>Our 30 day plan of correction included immediate attention to the medical record deficiencies. The ASC Director presented the deficiencies to the ASC staff during the staff meeting on March 5, 2012. The ASC Director and CEO have communicated these deficiencies to the physicians as well as the need for immediate compliance following the survey. In addition, a process has been put into place (overseen by the ASC Director) to ensure that the charts are audited to ensure that all signatures, dates, time stamps, and checking of boxes are completed consistent with the surgery center policy. This auditing process will occur prior to marking the electronic health record "complete." Since the regularly scheduled Board meeting exceeded our 30 day plan of correction, our 31 - 60 day plan of correction includes the formal presentation of the medical record deficiencies to the Board as well as the Medical Staff on March 19, 2012. During this meeting, the policy specific to</p>	03/05/2012			

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	<p>admitted 07/20/11, indicated a nurse's signature, date, and time on the printed orders Page 2, but lacked the "Discharge" box being checked as ordered and the physician signature was dated the day after discharge.</p> <p>5.. The medical record for patient #N15, admitted 10/04/11, indicated a nurse's signature on the Pre-Op Nursing Notes, but lacked documentation of a date or time.</p> <p>6. The medical record for patient #N16, admitted 10/04/11, indicated both a nurse's and physician's signature, date, and time on the printed orders Page 2, but lacked the "Discharge" box being checked as ordered.</p> <p>7. The medical record for patient #N20, admitted 11/16/11, indicated printed discharge orders signed, dated, and timed by a nurse, but lacked a signature, date, or time from a physician.</p> <p>8. The medical record for patient #N21, admitted 11/17/11, indicated a physician's signature on the printed orders Page 2, but lacked the "Discharge" box being checked as ordered and lacked a date and time and a nurse's signature, date, and time.</p> <p>9. The medical record for patient #N22,</p>		<p>signing, dating and time stamping will be reviewed in order to ensure their awareness to the requirements of authenticating the electronic health record in the surgery center.</p>	

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	<p>admitted 11/30/11, indicated dates and times, but lacked a physician's signature on the printed Pre-Op Orders and lacked a date or time for the nurse's signature. The printed Orders Page 2 indicated dates and times, but lacked physician signatures.</p> <p>10. The medical record for patient #N23, admitted 12/12/11, lacked a physician's signature on the H&P update.</p> <p>11. The medical record for patient #N25, admitted 12/20/11, indicated a nurse's signature, date, and time on the printed orders Page 2, but lacked a physician's signature, date, and time.</p> <p>12. The facility policy titled "Medical Records, last reviewed November 15, 2010, indicated, "...A medical record shall be maintained for each patient, which is accurate, legible, complete, and comprehensive to ensure adequate patient care ...All entries in the Medical Record related to patient care and treatment provided are to be dated and authenticated by the author."</p> <p>13. At 9:30 AM on 02/16/12, staff member #A1 confirmed the medical record findings and indicated all of the boxes on the electronic medical record charting should be completed.</p>			

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S0816	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(c)(1)(C)</p> <p>The medical staff shall write and implement policies and procedures and the governing body shall approve policies and procedures which include but are not limited to, the following:</p> <p>(C) Personnel permitted to administer anesthesia. Anesthesia must only be administered by an individual privileged by the medical staff and who is a:</p> <p>(i) qualified physician with appropriate training, experience, and privileges;</p> <p>(ii) practitioner holding a current permit to administer a specific form of anesthesia or otherwise authorized to administer topical, local, regional, or general anesthesia by state law or rule; or</p> <p>(iii) registered nurse acting under the direction of and in the immediate presence of the operating physician or other physician and who holds a certificate of completion of a course in anesthesia approved by the American Association of Nurse Anesthetists or a course approved by the appropriate licensing board.</p> <p>Based on observation, document review, and staff interview, the facility failed to ensure 1 of 2 Certified Registered Nurse Anesthetists (CRNAs) was privileged to</p>	S0816	Upon review of the staff member credentialing file in question, all privileges were approved and granted by the Medical Staff and Board of Directors. It was	03/02/2012			

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	<p>administer topical, local, regional or general anesthesia (#5).</p> <p>Findings included:</p> <ol style="list-style-type: none"> Staff member #5 core privileges that were not marked approved by the medical staff on 5/11/2010 included: Monitoring Anesthesia Care; Administer general anesthesia to adult and pediatric patients; administer regional anesthesia; and Support life functions including BLS, ACLS, PALS under stress of anesthesia. Staff member #5 was observed administering regional anesthesia on 2/15/2012 at 9:00 AM even though the request of core privileges was not marked approved for administering Regional anesthesia. At 11:00 AM on 2/16/2012, staff member #1 indicated staff member #5 administers general, regional, topical, and local anesthesia under supervision of a physician. 		<p>determined that a clerical/administrative oversight on page 3 occurred and the appropriate boxes were not completed at the time of reappointment. The Medical Director as well as the President have reviewed the credentialing packet of the CRNA in question and have dated, initialed and completed all check boxes consistent with the prior decision of the Board This occurred on March 2, 2012. Going forward, the ASC Director and CEO will ensure that during the credentialing process that all paperwork and documentation is completed at that time in order to ensure documents are in compliance with the State requirements.</p>		

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S1010	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on observation, policy review, and interview, the facility failed to follow their policy regarding multi-dose vials in the surgical department.</p> <p>Findings included:</p> <p>1. At the end of the surgical case observation, the following observations were made in OR #1:</p> <p>A. An opened, 10 milliliter (ml) vial of Succinylcholine on top of the anesthesia cart with a handwritten date of 12/18 and a small sticker with a handwritten date of 11/15 over the manufacturer's expiration date. The manufacturer's expiration date under the sticker was 1 Feb. 2012.</p> <p>B. An open 10 ml. vial of Rocuronium bromide with handwritten dates of 1/27/12 and 02/04/12 in the anesthesia drawer.</p> <p>C. An open, but not dated, 5 ml. vial of</p>	S1010	<p>Our 30 day plan included immediate attention to the Pharmacy Services Policy. This policy was reviewed and updated as of March 5, 2012. The ASC Director ensured that this policy was appropriately communicated to all staff members, including CRNA's, for their education through appropriate training at the staff meeting on March 5, 2012. Going forward, annual competency training will be added to the yearly list of items to be communicated to each staff member consistent with the pharmaceutical service requirements of the State. Our 31 - 60 plan of correction includes the presentation of these items to the Board and Medical Staff for their approval at their regularly scheduled meeting on March 19, 2012.</p>	03/05/2012			

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	<p>2% Lidocaine in the anesthesia drawer.</p> <p>2. The facility policy titled "Pharmacy Services", last reviewed November 15, 2010, indicated on page 2, ...D. Labeling ...When multi-dose vials are initially used they will be dated with the current date and will have an effective expiration date twenty-eight (28) days from the date of initial use or the expiration date printed on the vial, whichever is sooner."</p> <p>3. At 9:30 AM on 02/15/12, staff member #A5 indicated the 2 written dates on the of Rocuronium were probably the date the medication was taken out of the refrigerator and the date the vial was opened. He/she indicated vials had 60 days out of the refrigerator and 30 days after opening. He/she indicated the use of the sticker on the vial of Succinylcholine was not usually done and he/she did not know why it was placed over the manufacturer's expiration date.</p> <p>4. At 10:00 AM on 02/15/12, staff member #A1 indicated the facility's multi-dose policy was to date medication vials when opening and discard after 28 days. He/she confirmed the policy did not address the refrigerator 60 day dating.</p>						

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S1026	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(E)(i)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:</p> <p>(i) Drug cabinets must be accessible only to authorized personnel.</p> <p>Based on observation, policy review, and interview, the facility failed to ensure all medications were secured in locked cabinets.</p> <p>Findings included:</p> <p>1. During the tour of the pain procedure room at 9:45 AM on 02/15/12, accompanied by staff member #A1, a cabinet containing a large quantity of injectable medications, Lidocaine, Marcaine, Zofran, Robinul, Narcan, was observed without any locking device. The room also was not locked.</p> <p>2. The facility policy titled "Pharmacy</p>	S1026	<p>Immediately following the on-site survey, the Maintenance Coordinator added a lock to the cabinet in the procedure room on Saturday, February 18, 2012 in order to provide appropriate security for medications within a locked cabinet. The medications had been temporarily moved to an alternate locked area until the completion of the installation of the lock.</p>	02/18/2012	

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	<p>Services", last revised November 15, 2010, indicated on page 2, " C. Pharmacy Storage Cabinet All drugs will be stored in a locked pharmacy storage cabinet."</p> <p>3. At 9:45 AM on 02/15/12, staff member #A1 indicated the staff from the contracted cleaning service would clean in that room on Thursdays and acknowledged the cabinets did not lock to secure the medication.</p>			