STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	9-5137	A. BLDG: 00 B. WING:	04/29/2013

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BERGER & BENJAMIN LLP STATE LICENSE NUMBER: **00078701**	**1335 TABOR ROAD SUITE 202** **PHILADELPHIA, PA 19141**

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M 0000	INITIAL COMMENT This report is the result of an unannounced full Registration survey conducted on April 16, 2013, at Berger and Benjamin. It was determined that the facility was not in substantial compliance with the requirements of the Pennsylvania Department of Health Regulations § 28 Pa Code, Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics.	M 0000		
M 0032		M 0032		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: | (X6) DATE:

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M 0032	Continued from page 1 29.43(b) Facility Approval All medical facilities except hospitals may become approved facilities upon submission of an application to the Department from a person authorized to represent such facility and, at the discretion of the Department, satisfactory completion of an on-site survey. This REGULATION is not met as evidenced by:	M 0032	Plan of Correction: Berger and Benjamin ("BB") respectfully states that it is in compliance with the requirements of the Pennsylvania Department of Health Regulations 28 Pa. Code, Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. BB meets or exceeds the standards applicable to facilities that provide early abortion care using only local or topical anesthesia, as set forth in 18 Pa. C.S.A. §§ 3201-3220, 28 Pa. Code, Chapter 29, Subchapter D, 35 P.S. § 448.806(h)(1), and 28 Pa. Code §§ 551.3, 551.31. The facility maintains a safe and sanitary environment for patient care. BB submits this plan of correction in an effort to continually improve the excellence of its patient care, in cooperation with the Department of Health. 1) The facility's storage area is a locked room that is not used as an operating room or as a patient care area. The contents of the room	Completion Date: **06/01/2013** Status: **APPROVED** Date: **05/20/2013**

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M 0032	Continued from page 2	M 0032	present no life safety concern in the event of a fire. No patients have access to this room, and the ceiling tile in this room does not threaten the health or safety of any patients. Nonetheless, BB has requested that the ceiling tile in question be replaced with new ceiling tile. The temperature and humidity in this room are kept at a comfortable indoor level. Because this room is a storage area for supplies and equipment and because no patient care occurs in this room, it would serve no rational purpose to take continuous readings of the temperature and humidity in the room; in fact, requiring staff to monitor and document the temperature and humidity in a room that is used only for storage would pointlessly divert staff from their patient care duties and would be detrimental to patients. The portable ventilation unit is not being used and has been removed as has the ductwork. Nothing is stored in this room which is temperature or humidity sensitive. The worn	

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M 0032	Continued from page 3	M 0032	appearance of the vinyl coverings of the wheelchair is secondary to cleaning with caustic chemicals between patient use. The function is not affected, and the chemicals are necessary to assure cleanliness. 2) Because no sedation procedures are performed at BB, all patients are fully conscious and alert at all times. There is no need for patients to recover from the effects of moderate sedation, because no sedation is used. BB maintains a waiting area for post-surgical patients. Patients using this waiting area are not sedated, are fully clothed, and rest comfortably until they are ready to be discharged. BB does not provide privacy curtains in either its pre- or post-surgical waiting area; however, should a patient indicate a need for privacy, BB maintains a second-tier waiting room that is available upon request to grieving patients or families desiring a private space. In light of the Department's position that privacy curtains would provide a	

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M 0032	Continued from page 4	M 0032	better patient experience, BB is researching the possibility of the installation of privacy curtains in its post-surgical waiting area and anticipates that bids will be obtained by June 1, 2013. 3) BB disputes the characterization of its facility as having a "combined" clean and soiled work area. Rather, it uses two clearly separated areas, one for soiled instruments and one for clean instruments, within a single room. The room contains two separate sinks and two separate work counters. Used instruments are covered and moved from the procedure room to the soiled side of the instrument workroom, where the instruments are soaked, washed, and disinfected. Once clean and disinfected, the instruments are moved to the clean workspace, where the instruments are packaged, wrapped and sterilized in the autoclave. At no time are soiled instruments placed in the clean workspace. When autoclave sterilization is finished, the trays of	

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M 0032	Continued from page 5	M 0032	sterile instruments are then stored in a area designated for sterile equipment; at the Department's suggestion, this area will be relocated to a storage area in a separate room. The setup of the workroom, with separate work areas for soiled and clean instruments, is sufficient and appropriate to ensure that there is no cross-contamination of surgical instruments and supplies. Locating the clean and soiled work areas within a "U"-shaped configuration permits used instruments to be cleaned and transferred to the clean workspace without traversing patient care areas and without risking re-contamination. Patients passing by the workroom are under staff escort and are not permitted in the workroom. In addition, BB trains its staff in proper infection control protocols which it adopted under the guidance and direction of the Department of Health's Healthcare Associated Infection Prevention Section (HAIP). The health and safety of patients are thus protected	

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M 0032	Continued from page 6	M 0032	against the risk of infection by BB's separation of the clean and soiled functions into separate and distinct work areas and by the use of proper infection control protocols. The efficacy of these protocols is evidenced by BB's extraordinarily low post-surgical infection rate of 0.05%. Although BB maintains that it has already complied with the applicable standards, BB has addressed the Department's concerns by clearly labeling the clean and soiled work areas and by separating them with a visible divider at countertop level. 4) BB has addressed this concern by ordering the repair of the wood shelf directly above the autoclave. This repair will be completed by June 1, 2013. In addition, BB has relocated its wrapped sterile supplies to an acceptable storage area. No patient was subjected to any risk of harm. 5) BB has relocated the locked	

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M 0032	Continued from page 7	M 0032	storage cabinet containing lidocaine and boxes of needles to a locked storage area away from the vicinity of the soiled work area. 6) BB has ordered that the rip in the cover of the examination table be repaired. This repair will be completed by June 1, 2013. No patient was harmed or threatened by the rip in the covering of the examination table, which was covered with clean exam paper at all times patients were present. 7) BB stored medications in the refrigerator section of a refrigerator/freezer unit. No medications were stored in the freezer section containing biohazard material. To address the Department's concern, BB has moved biohazard materials to a completely separate refrigerator.	

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M 0032	Continued from page 8 Based on observation and interview with staff (EMP), it was determined the facility failed to ensure that patient privacy was provided and a safe and sanitary environment was maintained. Findings include: Observation tour of the facility on April 16, 2013, between 1:00 PM and 1:30 PM revealed the following: 1) Observation of the facility's storage area, which was the former Operating Room (OR)prior to the facility becoming a Class A facility, revealed a supply of intravenous fluid bags. There was no documentation of temperature and humidity for this supply room dated for 2013. There were brown stains on the ceiling tiles and a portable ventilation unit in the room had a flexible hose that exited the room through a ceiling tile. The storage area also contained an anesthesia machine. The examination table and wheelchair also stored in this room had a	M 0032		

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M 0032	Continued from page 9 worn appearance. Interview on April 16, 2013, at 1:05 PM, with EMP1 confirmed the former OR was being used as a storage room and the temperature and humidity had been previously documented until the facility became a Class A facility in December 2012. EMP1 confirmed the brown ceiling tiles, the portable ventilation unit's flexible hose exited through the ceiling tile and that the anesthesia machine was not being used for any procedures. EMP1 confirmed the worn appearance of the patient equipment was from solutions used for cleaning. 2) The patient recovery room area revealed seven patient recovery chairs for post-operative care. There were no cubicle curtains provided for privacy for the seven recovery chairs. Interview on April 16, 2013, at 1:10 PM, with EMP1 confirmed privacy curtains were not provided since the facility was now considered a Class A facility.	M 0032		

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M 0032	Continued from page 10 3) The soiled work area and the clean work area remained located together. Further observation of the area revealed the clean and soiled work areas were U shaped and were open to the hallway where patients and staff passed to access Procedure rooms A-1, A-2, and Exam 1. Interview on April 16, 2013, at 1:15 PM, with EMP1 confirmed the soiled and clean work areas remained located together. 4) The clean and soiled work area revealed wrapped sterile supplies stored directly on a wood shelf located directly above the autoclave. The wood shelf was covered with a torn disposable blue pad to cover shelf damage. Interview on April 16, 2013, at 1:15 PM, with EMP1 confirmed the wood shelf had not yet been replaced but covered with the disposable blue pad and the sterile supplies continued to be stored on this shelf.	M 0032		

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M 0032	Continued from page 11 5) Observation of the combined clean and soiled work area revealed a locked cabinet located over the sink that contained a supply of Lidocaine 1% and numerous boxes of various gauge size needles. Interview on April 16, 2013, at 1:10 PM, with EMP1 confirmed medication and needles continued to be stored in the combined clean and soiled work area. 6) Observation of Treatment Room A revealed the examination table had a rip across the width of the table that was covered with exam table paper. Interview on April 16, 2013, at 1:20 PM, with EMP1 confirmed the examination table was ripped. 7) Observation of the Medication Storage Biohazard Room revealed a refrigerator that contained various medications. The refrigerator's freezer contained plastic biohazard specimen containers waiting for pick up. There was an	M 0032		

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M 0032	Continued from page 12 additional empty small refrigerator also designated for specimen storage. There were red plastic sharps containers also located on the floor in this room. Interview on April 16, 2013, at 1:30 PM, with EMP1 confirmed the refrigerator contained medications and the refrigerator freezer contained biohazard specimen containers waiting for pick up.	M 0032		

Certified End Page

BERGER & BENJAMIN LLP

STATE LICENSE NUMBER: 00078701

SURVEY EXIT DATE: 04/29/2013

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Nancy J. Lescavage
Deputy Secretary for Quality Assurance

Rachel L. Levine, MD
Secretary of Health

pennsylvania
DEPARTMENT OF HEALTH

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